UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: CHANTIX (VARENICLINE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION (NO. II) *This Document Relates to All Actions*	22-MD-3050 (KPF) 22-MC-3050 (KPF) **OPINION AND ORDER**

KATHERINE POLK FAILLA, District Judge:

In this multidistrict litigation, Plaintiffs bring a host of claims against Defendant Pfizer in connection with Defendant's voluntary recall of the prescription drug Chantix, after the drug was found to be contaminated with excess levels of a nitrosamine known as N-nitroso-varenicline. Broadly, Plaintiffs allege that Defendant fraudulently and negligently misrepresented to consumers that Chantix was free of nitrosamines and was manufactured in accordance with current Good Manufacturing Practices ("cGMPs"), as required by the FDA and incorporated under various states' laws. Plaintiffs further maintain that the sale of contaminated Chantix breached express and implied warranties accompanying the product, and was done in violation of state consumer protection laws. To round things out, Plaintiffs also press claims for negligence, negligence *per se*, and unjust enrichment.

Now before the Court is Defendant's equally sweeping motion to dismiss Plaintiffs' Consolidated Master Class Action Complaint (the "CAC") in its entirety. For the following reasons, Defendant's motion is granted in part, most notably as to several of Plaintiffs' theories of misstatements undergirding their misrepresentation- and warranty-based claims. Separately, the Court orders

supplemental briefing on the issues of pre-suit notice and the economic loss rule, and withholds judgment on those issues accordingly.

BACKGROUND[1]

A. Factual Background

1. The Parties

Defendant Pfizer is a Delaware corporation, with its principal place of business in New York. (CAC ¶ 77). Defendant manufactures and distributes Chantix, a prescription drug designed to help consumers quit smoking, as discussed in greater detail in this section. (*Id.*).

Plaintiffs fall into two separate categories: (i) the Consumer Plaintiffs and (ii) the Third-Party Payor ("TPP") Plaintiffs. The Consumer Plaintiffs are natural persons residing in twelve states, and each alleges that he or she purchased Chantix as "sold, manufactured, and/or distributed into the United States supply chain by [Defendant]." (*See* CAC ¶¶ 24-46). The TPP Plaintiffs are entities that administer health benefit programs and their assignees. (*See id.* ¶¶ 47-76). Each of the TPP Plaintiffs alleges that it either purchased Chantix for the benefit of its members or reimbursed or paid for its members' purchases of Chantix. (*See, e.g.*, *id.* ¶ 48).

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[1] This Opinion draws its facts primarily from Plaintiffs' Consolidated Master Class Action Complaint ("CAC" (Dkt. #40)), the well-pleaded allegations of which are taken as true for purposes of this motion. *See Morrison* v. *Nat'l Austl. Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008); *see also Ashcroft* v. *Iqbal*, 556 U.S. 662, 679 (2009).

For ease of reference, the Court refers to Defendant's memorandum of law in support of its motion to dismiss as "Def. Br." (Dkt. #43); to the Declaration of Colleen M. Gulliver in Support of Defendant's Motion to Dismiss as "Gulliver Decl." (Dkt. #44); to Plaintiffs' memorandum of law in opposition to Defendant's motion to dismiss as "Pl. Opp." (Dkt. #49); and to Defendant's reply brief as "Def. Reply" (Dkt. #50).

2. Chantix

Chantix has been manufactured and distributed by Defendant in the United States since its approval by the United States Food and Drug Administration ("FDA" or the "Agency") in May 2006, pursuant to Defendant's new drug application ("NDA"). (CAC ¶ 3; Gulliver Decl., Ex. 1, 10). The active ingredient in Chantix is a compound known as varenicline, which acts as a partial nicotine agonist, helping to reduce the nicotine cravings associated with smoking. (CAC ¶ 2). Chantix's FDA-approved labeling specifies varenicline as its active ingredient, alongside a number of other inactive ingredients. (*Id.* ¶ 116; *see also* Gulliver Decl., Ex. 10 at 5). The labeling also indicates that Chantix is intended for short-term use only, and specifically advises that Chantix is designed to be taken for a period of twelve or twenty-four weeks, depending on the dosage. (Gulliver Decl., Ex. 10 at 21; *id.*, Ex. 11 at 1).

Chantix has been commercially successful and widely adopted, and Defendant has spent considerable resources marketing Chantix to medical professionals and the public. (CAC ¶¶ 4-5). The price for a 30-day supply of Chantix has climbed from around $113.98 at Chantix's launch to $485 in 2018; the drug brought in $997 million in sales in 2018 alone. (*Id.* ¶ 6). Furthermore, because Defendant successfully extended Chantix's patent exclusivity through August 2022, the product faced no generic competition for over 16 years. (*Id.* ¶ 115).

3. FDA's Investigation of Nitrosamines and Establishment of ADIs

Nitrosamines are semi-volatile chemicals that form during industrial and natural processes. (CAC ¶ 160). Nitrosamines have no known therapeutic benefit and, as relevant here, have been recognized as a carcinogen by the FDA, as well as other public health agencies in the United States and elsewhere. (*Id.* ¶¶ 161-162). Still, as the FDA has advised, "[n]itrosamines are common in water and foods," such that "[e]veryone is exposed to some level of nitrosamines" in their daily lives. (Gulliver Decl., Ex. 14 at 4).

In or around mid-2018, the FDA began investigating the presence of nitrosamines in medication. (CAC ¶ 168; Gulliver Decl., Ex. 15 (the "Nitrosamine Guidance") at 2). The FDA soon learned of the presence of a nitrosamine impurity in valsartan, an angiotensin II receptor blocker ("ARB") medication used to treat high blood pressure. (CAC ¶ 168; Nitrosamine Guidance 2). The discovery of nitrosamine contamination in valsartan led to a recall of that drug, as well as subsequent recalls of losartan and irbesartan, two related blood pressure medications that were also found to have been contaminated by nitrosamines. (CAC ¶ 168; Nitrosamine Guidance 2-3). At that time, the FDA issued guidance to manufacturers of ARB medications, advising those manufacturers to evaluate their products for nitrosamines. (CAC ¶ 168 n.72 (citing *General Advice Letter, ARB*, U.S. FOOD & DRUG ADMIN. (2019), *available at* https://perma.cc/M9Z7-8YR5)). The letter further warned manufacturers that "[d]ue to [nitrosamines'] potent carcinogenic effects, and because it is feasible to limit these impurities by taking reasonable steps to

prevent or eliminate their presence, FDA has determined that there is no acceptable specification for nitrosamines in ARB [active pharmaceutical ingredients] and [drug products]." *General Advice Letter, ARB*, U.S. FOOD & DRUG ADMIN.

In September 2019, the FDA learned that common heartburn products also contained unacceptable levels of nitrosamines and requested their voluntary recall from the market. (Nitrosamine Guidance 3). Three months later, in December 2019, the FDA became aware of international reports that some diabetes medicines containing the active ingredient metformin were reportedly affected by nitrosamine contamination. (*Id.*). Through its own testing, the FDA identified certain lots of metformin that contained nitrosamines above the Agency's recommended acceptable intake limit and requested the voluntary recall of those lots by their manufacturers. (*Id.*).

Given the increasing prevalence of the nitrosamine contamination issue, on September 3, 2020, the FDA issued a broader guidance document, titled *Control of Nitrosamine Impurities in Human Drugs; Guidance for Industry*, 85 Fed. Reg. 55017 (Sept. 3, 2020), which guidance the Agency updated in February 2021 in response to further, unexpected discoveries of nitrosamine impurities in other companies' medicines. (Nitrosamine Guidance 1). The Nitrosamine Guidance recommended that manufacturers of active pharmaceutical ingredients and drug products take steps to detect and prevent unacceptable levels of nitrosamine impurities in their products or to avoid their presence when feasible. (*Id.* at 11). In particular, the Nitrosamine Guidance

introduced a three-step process for mitigating nitrosamine impurities, pursuant to which process manufacturers were advised to: (i) "[a]ssess the risk of nitrosamine impurities in [] marketed products"; (ii) "[c]onduct confirmatory testing when there is any risk for the presence of nitrosamine impurities"; and (iii) "[r]eport changes implemented to prevent or reduce nitrosamine impurities in [drug products] to FDA." (*Id.*).

Additionally, the Nitrosamine Guidance set acceptable daily intake ("ADI") limits for certain nitrosamine impurities, to guide manufacturers in "determining limits for nitrosamine impurities in [active pharmaceutical ingredients] and drug products." (Nitrosamine Guidance 10). The ADI limits were calculated to represent the daily intake level of a nitrosamine that, if consumed every day for a period of 70 years, could create a theoretical lifetime cancer risk of 1 in 100,000. (*Id.* at App'x B). In setting these limits, however, the FDA recognized that cancer risk profiles in connection with these ADIs would vary in connection with dosage and term of use, and recommended that "[m]anufacturers [] prioritize evaluation of [active pharmaceutical ingredients] and drug products based on factors such as maximum daily dose, duration of treatment, therapeutic indication, and number of patients treated." (*Id.* at 9). The FDA noted, "[f]or example, a drug product with a [higher] maximum daily dose … with the same detected level of the same type of nitrosamine[,] would pose a greater risk than a drug product with a [lower] maximum daily dose …. A drug product intended for only short-term use (*e.g.*, a 7-day course of an

antibiotic) poses less risk than a drug product intended for chronic use." (*Id.* at 9 n.30).

In parallel with the FDA's investigation of nitrosamines, on October 26, 2020, Health Canada, the Canadian analogue to the FDA, asked all companies marketing varenicline (the active ingredient in Chantix) to evaluate the risk of the presence of nitrosamine impurities in their drug product and to conduct testing as necessary. (CAC ¶ 169 (citing *Champix (varenicline) — Potential Risk Posed by Long-Term Exposure to Nitrosamine Impurity, N-nitroso-varenicline, Exceeding Acceptable Intake Limits*, HEALTH CANADA (June 30, 2021) ("2021 Health Canada Notice"), *available at* https://perma.cc/5LKF-DVBA)).

4. Defendant's Discovery of Nitrosamine Impurities in Chantix, and Chantix's Voluntary Recall

On June 30, 2021, Health Canada published a notice to healthcare providers that "testing results received from Pfizer Canada ULC identified 5 lots of CHAMPIX (varenicline) with levels of a nitrosamine impurity, *N*-nitrosovarenicline ("NNV"), above the acceptable intake limit established by Health Canada." (2021 Health Canada Notice). "As a result, Health Canada requested that Pfizer Canada ULC recall the 5 impacted lots." (*Id.*).

Just two days later, on July 2, 2021, the FDA announced "Pfizer's voluntary recall of nine lots of … varenicline (brand name Chantix) … because [varenicline] may contain levels of [NNV] above FDA's acceptable intake limit." (Gulliver Decl., Ex. 3 at 1 ("July 2, 2021 Recall Notice"); CAC ¶¶ 14-16). In doing so, however, the Agency informed patients and health care professionals that "there is no immediate risk to patients taking this medication," inasmuch

as "[a]n increased cancer risk would be associated with long-term use, and the health benefits of stopping smoking outweigh the cancer risk from the nitrosamine impurity in varenicline." (July 2, 2021 Recall Notice 1). The notice further advised patients to "[c]ontinue taking [Chantix] until your doctor or pharmacist gives you a replacement or a different treatment option." (*Id.*).

On July 19, 2021, August 18, 2021, and September 17, 2021, Pfizer expanded the scope of its voluntary recall of Chantix, ultimately to include all lots of Chantix on the market. *See FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)*, U.S. FOOD & DRUG ADMIN. (last modified May 5, 2022), *available at* https://perma.cc/4L4G-Q8K8. In connection with each recall announcement, the FDA again advised "patients taking recalled varenicline [*i.e.*, Chantix] to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition." *Id.* The Agency likewise reiterated its reasoning for such advice, noting that "[t]he health benefits of stopping smoking outweigh the cancer risk from the nitrosamine impurity in varenicline." *Id.*

B. Procedural History

1. The *Harris* Litigation

On August 12, 2021, Plaintiff Rosalyn Harris, a New Jersey resident, brought an action against Defendant, seeking damages in connection with her purchase of Chantix. *See Harris* v. *Pfizer*, 586 F. Supp. 3d 231, 238 (S.D.N.Y. 2022). On November 10, 2021, the *Harris* complaint was amended to add Mary

Allen, a New York resident, as an additional plaintiff alleging the same claims. *Id.* Both plaintiffs "allege[d] that they did not know that Chantix contained [NNV] … and that they would not have purchased the medication if they had known it was contaminated." *Id.* Notably, while the *Harris* "plaintiffs' claims [arose] out of [Defendant's] recall of Chantix due to contamination from [NNV]," the *Harris* plaintiffs strategically brought "claims grounded in contract and fraud." *Id.* at 239. These claims "ha[d] the advantage (for the plaintiffs) that they [did] not require a showing of personal injury." *Id.* "They [did], however, require the plaintiffs to plausibly allege that [Defendant] represented or warranted that [its] product was free of nitrosamines — or at least that [Defendant] had a duty to disclose any nitrosamine contamination." *Id.*

In an Opinion and Order published on February 16, 2022, and as discussed further herein, Judge Denise Cote, to whom the *Harris* case was assigned, dismissed the complaint in its entirety. *Harris*, 586 F. Supp. 3d at 239. While Judge Cote found that the *Harris* plaintiffs had standing to sue, she held that they had failed to plausibly establish that Defendant had made any fraudulent statement or misrepresentation in connection with the nitrosamine contamination. *Id.* at 239-41. Most notably, Judge Cote rejected the *Harris* plaintiffs' allegations that Pfizer had made two misrepresentations in particular: "first, that the product [the plaintiffs] purchased was 'Chantix', as approved by the FDA; and second, that the product contained only the active ingredient varenicline." *Id.* at 240. Judge Cote observed that the "presence of a contaminant does not render the brand name on the label false —

contaminated Chantix is still Chantix," and concluded similarly that the *Harris* complaint "allege[d] no facts to suggest that the Chantix [that the plaintiffs had] purchased differs in any way from the drug approved by the FDA, much less that it differs so much as to no longer be Chantix." *Id.* at 241. Judge Cote further found that the *Harris* plaintiffs had failed to adequately allege that Defendant was under any duty to disclose the nitrosamine contamination, that Defendant had any fraudulent intent, or that Defendant had violated any warranty, express or implied, in connection with the sale of contaminated Chantix. *See generally id.* at 240-45.

2. The *Chantix* MDL

While the *Harris* action was pending, other purchasers of Chantix across the United States filed separate lawsuits in connection with Defendant's recall. In particular, the Consumer Plaintiffs filed separate lawsuits in the Southern District of New York, the Northern District of California, the Southern District of Florida, the Southern District of Illinois, the Eastern District of Pennsylvania, and the Western District of Pennsylvania. (*See* Dkt. #6, Schedule A). The TPP Plaintiffs also filed suits in the Southern District of New York and the District of New Jersey. (*Id.*).

On August 31, 2022, TPP Plaintiff County of Monmouth filed a motion before the United States Judicial Panel on Multidistrict Litigation (the "JPML"), pursuant to 28 U.S.C. § 1407, requesting an order transferring and centralizing all actions filed against Defendant stemming from Defendant's manufacture and sale of Chantix. *See In re Chantix (Varenicline) Mktg., Sales*

Pracs. and Prods. Liab. Litig., MDL No. 3050, Dkt. #1 (Aug. 31, 2022). On December 22, 2022, the JPML issued an order granting the motion, finding that "the[] actions involve common questions of fact, and that centralization in the Southern District of New York will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation." (Dkt. #76). Accordingly, all cases were transferred to and centralized before the undersigned. (*Id.*).

On January 6, 2023, the Court issued an order ("Order Number 1") setting forth a protocol for the consolidation of subsequent cases, establishing procedures for the filing and service of documents, and setting forth a schedule for preliminary steps in the action, including an initial pretrial conference and the filing of motions for the appointment of lead counsel. (Dkt. #6). In connection with that Order, the parties appeared before the Court for an initial pretrial conference on April 7, 2023. (*See* April 7, 2023 Minute Entry; Dkt. #36 (transcript of proceedings)). Thereafter, on May 1, 2023, the Court issued an order appointing lead counsel. (Dkt. #39).

On May 5, 2023, Plaintiffs filed the Consolidated Master Class Action Complaint, the operative pleading in this matter. (Dkt. #40). As detailed further herein, the CAC alleges nine counts stemming from Defendant's manufacture and sale of Chantix: *Count I*, Breach of Express Warranty; *Count II*, Breach of Implied Warranty; *Count III*, Violation of the Magnuson-Moss Warranty Act; *Count IV*, Fraud; *Count V*, Negligent Misrepresentation and Omission; *Count VI*, Violation of State Consumer Protection Laws; *Count VII*,

Negligence; *Count VIII*, Negligence *Per Se*; and *Count IX*, Unjust Enrichment. (*See generally* CAC ¶¶ 218-381).

On June 20, 2023, Defendant filed its motion to dismiss the CAC. (Dkt. #42-44). Thereafter, on August 4, 2023, Plaintiffs filed their memorandum of law in opposition to Defendant's motion to dismiss. (Dkt. #49). Finally, on August 25, 2023, Defendant filed its reply memorandum of law in further support of its motion to dismiss the CAC. (Dkt. #50).

DISCUSSION

A. Motions to Dismiss Under Rule 12(b)(6)

Generally speaking, when considering the adequacy of a complaint upon a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a court must (i) accept all of the complaint's factual allegations (but not legal conclusions) as true and (ii) determine whether it states a "plausible" claim for relief. *See Ashcroft* v. *Iqbal*, 556 U.S. 662, 678-79 (2009). In doing so, the court must always "draw all reasonable inferences in [the non-movant's] favor." *Faber* v. *Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011). Put slightly differently, the court's task is to "assess[] the legal feasibility of the complaint," not "weigh the evidence that might be offered to support it." *Glob. Network Commc'ns, Inc.* v. *City of New York*, 458 F.3d 150, 155 (2d Cir. 2006). This is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

"In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the

complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." *DiFolco* v. *MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010); *see also* Fed. R. Civ. P. 10(c) ("A copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes."); *see generally United States ex rel. Foreman* v. *AECOM*, 19 F.4th 85, 106 (2d Cir. 2021), *cert. denied*, 142 S. Ct. 2679 (2022). Beyond this narrow universe of materials, a court may also consider "facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence" and may "disregard allegations in a complaint that contradict or are inconsistent with judicially-noticed facts." *Exch. Listing, LLC* v. *Inspira Techs., Ltd.*, 661 F. Supp. 3d 134, 153 (S.D.N.Y. 2023) (internal quotation marks and citations omitted). Pertinent to the case at hand, judicially-noticeable facts include those contained in the FDA's announcements in connection with the Chantix recall, as set forth in the Agency's guidance documents and related statements on its official website. *Richardson* v. *N.Y.C. Bd. of Educ.*, 711 F. App'x 11, 14 (2d Cir. 2017) (summary order) (holding that judicial notice may be taken of "all public documents, promulgated by or binding on a government agency, and not subject to reasonable dispute"); *Wells Fargo Bank, N.A.* v. *Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 167 (S.D.N.Y. 2015) (observing that judicial notice may be taken of an official government website, as "the website's authenticity is not in dispute and 'it is capable of accurate and ready determination'" (quoting *Doron Precision Sys., Inc.* v. *FAAC, Inc.*, 423 F. Supp. 2d 173, 179 n.8 (S.D.N.Y. 2006))).

B. The Court Grants in Part and Denies in Part Defendant's Motion to Dismiss

Defendant raises a number of challenges to the CAC, some applicable to all nine of Plaintiffs' claims, and some unique to individual claims. For the sake of efficiency, and given the interrelatedness of Plaintiffs' claims, the Court's analysis is divided into three general sections: *First*, the Court provides an overview of Plaintiffs' substantive theories of misrepresentation and breach of warranty as incorporated generally across Plaintiffs' various claims. *Second*, the Court considers Defendant's general arguments that apply across all claims in the CAC, finding that while Plaintiffs have established and adequately alleged a compensable injury, the preemptive effect of the federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. §§ 301-399i, limits Plaintiffs' actionable theories of misrepresentation and breach of warranty to those arising from specific manufacturing-related allegations. *Third*, the Court evaluates Defendant's claim-specific arguments across the nine substantive counts of the CAC.

The *Harris* decision looms in the background of both sides' arguments. Defendant maintains that this case is virtually identical to *Harris*, arguing that "[t]he key allegations in *Harris* and this MDL are the same," such that the outcome of this case should be the same as that of *Harris*. (Def. Br. 8-9). Plaintiffs counter that their complaint "features all the allegations that Judge Cote believed the *Harris* complaint lacked." (Pl. Opp. 3). The Court, for its part, finds that each party has used the logic of *Harris* to varying degrees of success, and discusses each party's efforts to plead around *Harris* throughout

its analysis below. Of most importance, the Court concludes that Plaintiffs have adequately pleaded a narrow set of claims in connection with alleged violations of certain Current Good Manufacturing Practices, which violations were not expressly addressed in *Harris*. That said, Plaintiffs are unavailing in their effort to relitigate *Harris*'s rejection of Plaintiffs' alleged misstatements in connection with Defendant's use of the Chantix brand name.

1. Defendant's Alleged Misstatements

As in *Harris*, Plaintiffs press claims predominantly grounded in contract and fraud, including claims for breach of express and implied warranty, fraudulent and negligent misrepresentation, and violation of state consumer protection statutes. To proceed with each of these claims, Plaintiffs must plausibly allege either that Defendant made specific representations or warranties pertaining to Chantix that ultimately turned out to be false, or that Defendant had a duty to disclose the issues associated with Chantix's nitrosamine contamination. *See Harris*, 586 F. Supp. 3d at 239. To do so, Plaintiffs rely on three general sets of misstatements, herein referred to as the "Sameness Misstatement," the "Active Ingredient Misstatement," and the "cGMP Misstatement." For ease of reference, the Court first summarizes each alleged misstatement before considering their sufficiency in Sections B.2 and B.3, *infra*.

a. The Sameness Misstatement

The first misrepresentation upon which Plaintiffs' contract and fraud-based claims rely is the Sameness Misstatement, *i.e.*, that Defendant, by selling

the contaminated product under its brand name, Chantix, represented and warranted to consumers that the product contained therein was Chantix. In Plaintiffs' estimation, Defendant breached this warranty and contradicted its representations when it sold Chantix contaminated with nitrosamines. The Sameness Misstatement should appear familiar, as it is virtually the same argument made by the *Harris* plaintiffs and rejected by the *Harris* court, as discussed *supra*.

To salvage this claim, Plaintiffs advance a sweeping theory in an effort to refute the *Harris* court's finding that the "presence of a contaminant does not render the brand name on the label false — contaminated Chantix is still Chantix." 586 F. Supp. 3d at 241 (finding that plaintiffs there had "allege[d] no facts to suggest that the Chantix [plaintiffs] purchased differs in any way from the drug approved by the FDA, much less that it differs as much as to no longer be Chantix"). Essentially, Plaintiffs now argue that the presence of nitrosamine contaminants in Chantix in fact rendered Chantix so different that it should be considered to be a "new and unapproved drug with additional active ingredients (such as nitrosamines in the subject [Chantix]) [that] cannot have the same label as the brand-name drug, as the two products are no longer the same and do not share therapeutic equivalence (*e.g.*, do not have the same safety profile)." (CAC ¶ 137; *see also id.* ¶ 150 (alleging that contaminated Chantix should be understood as "a different, new unapproved drug not

therapeutically equivalent to FDA-approved Chantix")).[2] To do so, Plaintiffs rely on the FDA's standard for "therapeutic equivalence," used in connection with the Agency's process for approval of new pharmaceuticals, as discussed further in Section B.2.ii, *infra*. (*See id.* ¶¶ 8-10 (discussing the therapeutic equivalence standard)).

b. The Active Ingredient Misstatement

Plaintiffs also advance the Active Ingredient Misstatement, which purports that nitrosamines were an active ingredient that should have been disclosed in Defendant's labeling of Chantix. (*See, e.g.*, CAC ¶ 141 ("The presence of additional active ingredients (N-nitroso-varenicline and nitrosamines) and potentially other deviations from Defendant['s] [New Drug Application] rendered [contaminated Chantix] of a lesser quality FDA-approved Chantix."); *see also id.* ¶¶ 116 ("Chantix's FDA-approved labeling specifies the active and inactive ingredients. Neither N-nitroso-varenicline nor N-Nitroso-dimethylamine [] nor any other nitrosamine is listed among the FDA-approved ingredients nor are any of these contaminants FDA-approved ingredients of Chantix."), 135-138 (discussing FDA regulations that require the amendment of a drug's label upon the addition of a new active ingredient)). In this regard, Plaintiffs allege that Defendant's labels of Chantix were false or misleading,

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[2] Indeed, in doing so Plaintiffs adopt the semantic approach of referring to Defendant's product throughout the CAC as a varenicline-containing drug (or "VCD") rather than contaminated Chantix, or simply Chantix. (CAC at 1). For example, Plaintiffs allege that "[Defendant] represented and warranted to consumers and TPPs that its VCDs [*i.e.*, contaminated Chantix] were therapeutically equivalent to, and otherwise the same as, the actual FDA-approved brand name drug Chantix." (*Id.* ¶ 7).

inasmuch as those labels represented and warranted to consumers that the only active ingredient was varenicline, and made no mention of nitrosamines, notwithstanding the present of the contaminant in the product that was marketed and sold. (*See, e.g.*, *id.* ¶ 191 ("Defendant affirmatively misrepresented and warranted to purchasers … that [Chantix] … did not contain (or [was] not likely to contain) any ingredient besides those identified on the products' FDA-approved labels.")).

c. The cGMP Misstatement

Finally, Plaintiffs allege the cGMP Misstatement, *i.e.*, that Defendant misrepresented its adherence to current Good Manufacturing Practices in its manufacturing of Chantix. (*See, e.g.*, CAC ¶ 222 (alleging that Defendant's labeling of Chantix "did not disclose known or knowable risks relating to nitrosamine contamination and that [Chantix was] not manufactured in a cGMP-complaint manner")). Of potential note, this theory relies on allegations that Defendant, by selling Chantix as an FDA-approved pharmaceutical, necessarily represented and warranted to consumers that it had been manufactured in accordance with cGMPs, a set of standards that must be followed by FDA-approved manufacturers. (*See id.* ¶ 225 (alleging that "the very fact that Defendant sold [Chantix] in the stream of commerce warranted [Chantix] [was] cGMP-compliant," given that such compliance is necessary to meet FDA quality assurance standards); *see also id.* ¶¶ 118-125 (discussing incorporation of cGMPs into the FDA's regulatory framework), 176-185 (same)). Plaintiffs further note that these standards have been adopted by various

parallel state regulatory frameworks. (*See id.* ¶ 288 (collecting citations to "state drug regulation laws [that] impose an independent duty on manufacturers to ensure that end purchasers (or their insureds) receive drugs that are made in accordance with cGMPs")). As a general matter, Plaintiffs assert that the presence of nitrosamines in Chantix supports their allegations that Defendant did not in fact adhere to specific cGMP requirements, belying Defendant's representation and warranty to consumers regarding the processes by which Chantix was manufactured.

2. Defendant's General Arguments

With these broad sets of misstatements in mind, the Court turns to the series of cross-cutting, threshold arguments raised by Defendant. Each of these general arguments, Defendant maintains, supports dismissal of all, or at least the vast majority of, Plaintiffs' claims. In particular, Defendant argues that: (i) Plaintiffs have not pleaded a compensable injury; (ii) Plaintiffs lack standing for a nationwide class or to seek injunctive relief; (iii) the FDCA preempts certain of Plaintiffs' claims; and (iv) Plaintiffs have not established that Defendant made any misrepresentations in connection with its manufacture and sale of Chantix. The Court addresses each set of arguments in turn.

a. Plaintiffs Have Plausibly Alleged a Compensable Injury

The Court begins with Defendant's challenges to the sufficiency of the injuries suffered by Plaintiffs. While Defendant concedes that this argument does not attack Plaintiffs' Article III standing to sue, it maintains that Plaintiffs'

failure to allege a compensable injury nonetheless requires dismissal of their claims on the merits, as the existence of compensable injury is a necessary element of each claim. (Def. Br. 16; Def. Reply 3-4). Defendant's concerns, however, are largely aimed at the underlying merits of Plaintiffs' claims and are thus overstated at the motion to dismiss stage, where Plaintiffs' well-pleaded allegations must be credited, and disputed inferences drawn in Plaintiffs' favor. As set forth below, the Court finds that Plaintiffs have met their threshold obligations to plead a plausible injury in connection with their purchases of Chantix.

i. Consumer Plaintiffs Have Plausibly Alleged Their Purchase of Chantix

Defendant's first challenge on the issue of compensable injury pertains to the sufficiency of the facts alleged in the CAC. Specifically, Defendant argues that the Consumer Plaintiffs have not plausibly alleged that they suffered any compensable injury because they have failed to establish that they purchased Chantix in the first place. (Def. Br. 16-17).[3] The Court, upon its own review of the CAC, is not so convinced.

In relevant part, each Consumer Plaintiff alleges that, "[d]uring the class period, [he or she] paid money for one or more of [Defendant's] VCDs [*i.e.*, Chantix] and purchased [Defendant's] VCDs [*i.e.*, Chantix]. The product

[3] Defendant does not dispute the plausibility of the TPP Plaintiffs' allegations in connection with their reimbursements for purchases of Chantix, examples of which transactions, the Court notes, are specifically alleged in the CAC. (*See* Pl. Br. 16-17; *see, e.g.*, CAC ¶ 49 (providing a table of transactions in which "[TPP] County of Monmouth received a request to reimburse a prescription drug on behalf of an enrollee for a particular date of service")).

purchased bore a unique National Drug Code … which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by [Defendant]." (CAC ¶ 24; *see also id.* ¶¶ 25-46 (repeating the same allegations for each Consumer Plaintiff)). Each Consumer Plaintiff further alleges that, had he or she been aware that the product "was contaminated with a nitrosamine and not made in a cGMP-complaint manner, … [he or she] would not have paid for [the product]." (*Id.* ¶ 24; *see also id.* ¶¶ 25-46).

Defendant maintains that these allegations do not plausibly establish a compensable injury because they lack specific details, such as the date of the transaction, the amount purchased, or the price paid. (Def. Br. 16-17). Defendant suggests that, absent this information, the Consumer Plaintiffs' simple recollection that they purchased Chantix at some point in time is implausible.

Defendant relies on three cases to underscore its point. (Def. Br. 16-17 (citing *Calcano* v. *Swarovski N. Am. Ltd.*, 36 F.4th 68 (2d Cir. 2022); *Wilson* v. *Mastercard Inc.*, No. 21 Civ. 5930 (VEC), 2022 WL 3159305 (S.D.N.Y. Aug. 8, 2022); *Colella* v. *Atkins Nutritionals, Inc.*, 348 F. Supp. 120 (E.D.N.Y. 2018)). Upon closer review, however, the cases are not nearly as supportive of Defendant's argument as Defendant makes them out to be. In the first, *Calcano* v. *Swarovski North America Ltd.*, the Second Circuit rejected a plaintiff's conclusory attempt to "parrot the [Second Circuit's] language" setting the standard for injury-in-fact, without providing any supporting factual

allegations in the complaint. 36 F.4th at 76 (citing *Kreisler* v. *Second Ave. Diner Corp.*, 731 F.3d 184, 188 (2d Cir. 2013)).

Similarly, the district court in *Wilson* v. *Mastercard Inc.*, found that the plaintiff had failed to establish that she had suffered any compensable injury on the basis of an alleged credit card overcharge. 2022 WL 3159305, at *4. The *Wilson* court, applying *Calcano*, found that the plaintiff's sole allegation pertaining to a credit card overcharge for a foreign exchange transaction was implausible when read with "reference to the broader factual context of the complaint." 2022 WL 3159305, at *4 (citing *Calcano*, 36 F.4th at 75). In particular, the court found the complaint lacked "[any] details to support [plaintiff's] conclusory assertion that the currency conversion rate was higher than the applicable wholesale rate," and therefore provided no plausible support for the alleged overcharge that was the basis for the plaintiff's injury. *Id.*

Finally, in *Colella* v. *Atkins Nutritionals, Inc.*, the district court found that the plaintiff there had failed to establish that he had suffered any compensable injury on the basis of an alleged purchase of a mislabeled food product. 348 F. Supp. 3d at 128-29. The *Colella* court rejected the plaintiff's sparse allegations that, at some point in a two-year period preceding the filing of his complaint, he had purchased three allegedly mislabeled diet snack products from a Wal-Mart store in Nassau County, New York. *See id.* at 128. As in *Wilson*, the *Colella* court found the plausibility of the plaintiff's allegations to be undercut by the broader context of his complaint. *Id.* at 142. In particular, the *Colella*

court noted that the plaintiff had failed to allege that the offending label was actually present on "any of [defendant's] products he alleges he purchased, and, instead allege[d] that an 'identical or *substantially similar* claim appears' on [such] product[s].'" *Id.* (citation omitted).

Considered together, these cases demonstrate that a plaintiff's failure to allege certain details in connection with a consumer transaction may be *sufficient* to undercut the plausibility of that plaintiff's allegations that he or she actually purchased a product. These cases do not, however, set forth the details *necessary* to plausibly plead a compensable injury in the context of a consumer transaction; concluding as much would effectively impose a heightened pleading standard beyond that which is required by the Federal Rules of Civil Procedure.[4] Rather, "[a]ssessing plausibility is 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Calcano*, 36 F.4th at 75 (quoting *Iqbal*, 556 U.S. at 679).

Applying this experience and common sense in its review of the CAC, the Court finds that the Consumer Plaintiffs have plausibly alleged that they purchased Chantix. Chantix is a brand-name pharmaceutical that cannot be purchased without a prescription, and was the only formulation of varenicline available on the market prior to the relatively recent FDA approval of generic varenicline. (*See* CAC ¶ 115 ("The FDA approved Chantix in May 2006.

[4] The Court recognizes that Federal Rule of Civil Procedure 9(b) requires increased specificity in connection with Plaintiffs' claims of fraud. As the Court finds, *infra*, that Plaintiffs' fraud claims must be dismissed for failure to adequately allege that Defendant acted with fraudulent intent, it need not reach the issue of whether the Consumer Plaintiffs' generalized allegations regarding their purchases of Chantix are sufficient to meet the requirements of Rule 9(b).

[Defendant] later succeeded in extending its patent exclusivity for Chantix through August 2022, meaning Chantix has not faced generic drug competition since its launch.")). Accordingly, each Consumer Plaintiff's recollection that he or she purchased Chantix is more plausible than, for instance, the allegations of the *Colella* plaintiff, who merely alleged that he purchased three over-the-counter food products at a Wal-Mart in a two-year period, none of which actually featured the particular labels at issue in the complaint. 348 F. Supp. 3d at 129, 142 (observing that "[p]laintiff fails to allege the actual … claims of any of the … products he alleges he purchased, and instead alleges that an 'identical or substantially similar claim appears' on the product"). The Court accepts the Consumer Plaintiffs' well-pleaded allegations as true, and finds that each Consumer Plaintiff has plausibly established that he or she did in fact purchase Chantix, and would not have purchased Chantix had he or she been aware that it was contaminated with a nitrosamine. (*See id.* ¶¶ 24-46).

Ultimately, the dates of each Consumer Plaintiffs' purchase will be ascertained through discovery, and will be pertinent in both the class certification and summary judgment stages of this litigation. To the extent that the Consumer Plaintiffs cannot adduce sufficient facts at those stages, the Court may revisit Defendant's arguments in favor of dismissal. Moreover, as the exact dates of each Consumer Plaintiff's purchases are disclosed, Defendant may raise arguments pertaining to any applicable statutes of limitations, as appropriate.

ii. Plaintiffs Have Plausibly Alleged Damages

Defendant's second set of challenges to the element of compensable injury addresses Plaintiffs' specific theories of economic damages. *First*, Defendant challenges Plaintiffs' theory that they did not receive the expected benefit of their bargain in purchasing Chantix, because the nitrosamine contamination reduced the drug's value. In Defendant's view, this theory fails because Plaintiffs did, in fact, receive the benefit of their bargain when purchasing Chantix. *Second*, Defendant disputes Plaintiffs' alternative theory that they were injured by paying a premium for Chantix that they would not have paid knowing of Chantix's contamination, which theory Defendant asserts is foreclosed by the nature of the prescription drug market. In making both arguments, Defendant is careful to clarify that it is not attacking Plaintiffs' standing to assert their claims, recognizing the *Harris* court's rejection of Defendant's similar arguments previously made in the standing context. 586 F. Supp. 3d at 239.[5]

This Court, however, is unmoved by Defendant's effort to revive substantially the same arguments that Judge Cote rejected in *Harris* by simply training them on a different element of Plaintiffs' *prima facie* case. First, as to Plaintiffs' benefit-of-their-bargain theory, numerous courts have rejected

[5] To wit, in *Harris*, Defendant argued that the complaint did not plausibly allege an injury-in-fact, as "the plaintiffs received the full benefit of the bargain," and could not otherwise plead a specific price premium. Yet the *Harris* court found both arguments insufficient to negate plaintiffs' alleged injury-in-fact, observing that both arguments "go[] to the merits of the plaintiffs' claims, not their standing to bring them." *Harris* v. *Pfizer*, 586 F. Supp. 3d 231, 239 (S.D.N.Y. 2022).

similar merits-based arguments that damages cannot be plausibly alleged where a contaminated product fulfilled its primary purpose, such that "plaintiffs got the benefit of their bargain." *Clinger* v. *Edgewell Pers. Care Brands, LLC*, No. 21 Civ. 1040 (JAM), 2023 WL 2477499, at *15 (D. Conn. Mar. 13, 2023) (finding unpersuasive defendants' "argu[ment] that the plaintiffs got the benefit of their bargain [when] they purchased [benzene-contaminated] sunscreen to protect them from the risks of sun exposure, and that is what the product did"); *see also In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.* ("*Valsartan III*"), MDL No. 2875 (RBK), 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021) (finding that "contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for"); *In re Metformin Mktg. & Sales Prac. Litig.* ("*Metformin*"), No. 20 Civ. 2324 (MCA), 2022 WL 970281, at *12 (D.N.J. Mar. 30, 2022) (adopting the court's finding in *Valsartan III*). As was aptly put in *Clinger*, "[t]his argument misses the point," as Plaintiffs' claims for damages arise from their allegations that "the [product] was defective in some way and therefore worth less than the price the [P]laintiffs paid for it," rather than their allegations that the product was entirely non-functional. 2023 WL 2477499, at *15 (citation omitted).

Here, a review of the CAC indicates that Plaintiffs' benefit-of-their-bargain theory is consistent with that found to be cognizable in *Clinger*, *Valsartan*, and *Metformin*, namely that had Plaintiffs been aware of the truth regarding Chantix's contamination, they would have either forgone their

purchase of the drug, or paid less for it, given that its contamination rendered it "inferior to what [Defendant] had promised." *Duran* v. *Henkel of Am., Inc.*, 450 F. Supp. 3d 337, 351 (S.D.N.Y. 2020). (*See, e.g.*, CAC ¶¶ 24 (alleging that the presence of the nitrosamine contaminant rendered the product "worth less," and that had Plaintiff known about the impurities, he would not have paid for Chantix), 231 (similarly alleging that "Plaintiffs and each member of the Class would not have … paid for [Chantix] had they known" of its contamination, and "did not receive the expected benefit of the bargain" as the presence of nitrosamine contamination rendered Chantix "worthless (or alternatively, certainly worth less")]). Accepting these well-pleaded allegations as true and drawing all inferences in favor of Plaintiffs, the Court finds that Plaintiffs have plausibly established that they suffered an economic injury in connection with their purchase of Chantix.

As to Plaintiffs' price premium theory — that Plaintiffs were injured by paying a premium for Chantix that they would not have paid knowing of Chantix's contamination — Defendant asserts that the lack of a competitive market for Chantix renders a price premium theory of damages implausible. (Def. Br. 21-22). The Court will not reject Plaintiffs' claims on this basis, however, as at the pleading stage "[t]here is no requirement that [a] [p]laintiff specify the exact amount of the price premium that [she] paid, *or a comparable product*." *Izquierdo* v. *Panera Bread Co.*, 450 F. Supp. 3d 453, 465 (S.D.N.Y. 2020) (emphasis added). Rather, all that Rule 8 requires is for the plaintiff to plead an injury and "a demand for the relief sought." Fed. R. Civ. P. 8(a).

Ultimately, Defendant's arguments present fact-based challenges to Plaintiffs' claimed injuries that are ill-suited for resolution on a motion to dismiss. Of course, Defendant may later challenge Plaintiffs' theories of injuries based on a more fully developed record. As concerns the motion to dismiss, however, the Court finds that Plaintiffs "have alleged enough at this stage to 'raise a reasonable expectation that discovery will reveal evidence' supporting their claim," and therefore have adequately alleged the existence of a compensable injury. *Fishon* v. *Peloton Interactive, Inc.*, No. 19 Civ. 11711 (LJL), 2020 WL 6564755, at *11 (S.D.N.Y. Nov. 9, 2020) (quoting *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 556 (2007)).

b. Plaintiffs Have Standing to Represent Out-of-State Class Members, but Not to Seek Injunctive Relief

Next, Defendant raises narrower standing challenges, arguing that irrespective of the compensable injury issue, Plaintiffs lack standing to pursue claims on behalf of a nationwide class, or to seek injunctive relief. (Def. Br. 28-29). Specifically, Defendant maintains that "Plaintiffs do not have standing to: (a) assert claims under laws of states where the Consumer Plaintiffs or the TPP's insureds did not fill their prescriptions; or (b) seek injunctive relief." (*Id.* at 28). The Court addresses each challenge in turn, finding ultimately that Plaintiffs have standing to proceed on behalf of absent class members, but lack standing to seek injunctive relief.

The standing requirement is grounded in Article III of the United States Constitution, which "limits federal courts' jurisdiction to 'cases' and 'controversies.'" *Ret. Bd. of the Policemen's Annuity & Benefit Fund of the City*

of Chi. v. *Bank of N.Y. Mellon*, 775 F.3d 154, 159 (2d Cir. 2014) (citing U.S. Const. art. III, § 2). To establish standing, a federal court plaintiff must demonstrate a "personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *DaimlerChrysler Corp.* v. *Cuno*, 547 U.S. 332, 342 (2006). The standing requirement ensures, *inter alia*, "that a plaintiff has a sufficiently personal stake in the outcome of the suit so that the parties are adverse." *Retirement Bd.*, 775 F.3d at 159-60 (quoting *W.R. Huff Asset Mgmt. Co.* v. *Deloitte & Touche LLP*, 549 F.3d 100, 107 (2d Cir. 2008)).

While standing is generally an individualized analysis, in a putative class action like this one, a plaintiff must also establish class standing through plausible allegations "[i] that [she] personally has suffered some actual injury as a result of the putatively illegal conduct of the defendant, and [ii] that such conduct implicates the same set of concerns as the conduct alleged to have caused injury to other members of the putative class by the same defendants." *Retirement Bd.*, 775 F.3d at 161 (quoting *NECA-IBEW Health & Welfare Fund* v. *Goldman Sachs & Co.*, 693 F.3d 145, 162 (2d Cir. 2012)). When this two-part test is satisfied, "the named plaintiff's litigation incentives are sufficiently aligned with those of the absent class members that the named plaintiff may properly assert claims on their behalf." *Id.*

Consistent with the standard applied to motions to dismiss under Rule 12(b)(6), to establish standing, a plaintiff must only allege enough facts to make it plausible for the court to conclude, using its judicial experience and common

sense, that the plaintiff has standing, and thus may survive a related motion under Rule 12(b)(1). *See Maddox* v. *Bank of N.Y. Mellon Tr. Co., N.A.*, 19 F.4th 58, 65-66 (2d Cir. 2021); *Calcano*, 36 F.4th at 75 ("Assessing plausibility is 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense."). Moreover, the court must accept all factual allegations in support of a plaintiff's standing as true and must draw all reasonable inferences in favor of the plaintiff. *See Calcano*, 36 F.4th at 72 n.1 (citing *Carter* v. *HealthPort Techs., LLC*, 822 F.3d 47, 56-57 (2d Cir. 2016)); *Sonterra Cap. Master Fund Ltd.* v. *UBS AG*, 954 F.3d 529, 533 (2d Cir. 2020).

Upon a review of the allegations in the CAC, the Court finds that the named Plaintiffs have readily demonstrated that they have standing to pursue claims on behalf of absent class members. Plaintiffs allege that their injuries arise out their common purchase of Chantix; they identify Defendant as the single source of the allegedly illegal conduct; and they assert that "the proof contemplated for all of the claims would be sufficiently similar." *Retirement Bd.*, 775 F.3d at 161 (citing *NECA*, 693 F.3d at 164). These allegations are sufficient to meet the pleading standard for class standing in this Circuit.

While Defendant is correct that choice-of-law issues may hamper Plaintiffs' ability to represent certain class members, such concerns are pertinent to the Court's class *certification* analysis, at a later stage in this litigation. The class *standing* inquiry, on the other hand, "derives from constitutional standing principles" and "is thus distinct from the criteria that govern whether a named plaintiff is an adequate class representative under

Rule 23(a)." *Retirement Bd.*, 775 F.3d at 161 (citing *NECA*, 693 F.3d at 158 n.9). The Court therefore finds that Plaintiffs may continue with their claims on behalf of out-of-state, absent class members.

The same cannot be said, however, for Plaintiffs' claims seeking injunctive relief. A plaintiff "must demonstrate standing separately" for "each form of relief sought." *Nicosia* v. *Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016) (citing *Friends of the Earth, Inc.* v. *Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000)). "Although past injuries may provide a basis for standing to seek money damages, they do not confer standing to seek injunctive relief unless the plaintiff can demonstrate that she is likely to be harmed again in the future in a similar way." *Id.*

Here, as Defendant notes, Plaintiffs are already aware of the purported contamination of the Chantix in their possession, and any unsold Chantix has been recalled by Defendant. (Def. Br. 29). Accordingly, the risk of future harm in connection with any purchase of Chantix is *de minimis*. *See Nguyen* v. *Algenist* LLC, No. 22 Civ. 13 (KPF), 2022 WL 17251733, at *4 (S.D.N.Y. Nov. 28, 2022) (noting that, once plaintiffs know the truth, they "cannot be misled"). Nor does Plaintiffs' unsupported suggestion that Defendant might "intend[] to resume selling [Chantix]" raise anything more than the faint specter of future harm, which comes up far short of the showing necessary to establish standing. (Pl. Opp. 19). *Cf. TransUnion LLC* v. *Ramirez*, 594 U.S. 413, 435-39 (2021) (finding that plaintiffs lacked standing to pursue claims for damages where their allegations set forth only a risk of future harm that had not yet

materialized). The Court, therefore, dismisses Plaintiffs' claims for injunctive relief without prejudice.

c. Certain of Plaintiffs' Claims Are Preempted

Having largely rejected Defendant's arguments concerning compensable injury and standing, the Court next considers Defendant's preemption-related challenges. As set forth below, the Court finds that, while the claims brought in connection with the Sameness Misstatement and the Active Ingredient Misstatement are preempted by the FDCA, Plaintiffs have sufficiently threaded the preemption needle by alleging parallel claims predicated on the cGMP Misstatement.

i. Implied Preemption Under the FDCA

The Court begins by considering the relevant law. The Supremacy Clause of the United States Constitution provides that "the Laws of the United States," as well as treaties and the Constitution itself, "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2; *see also Oneok, Inc.* v. *Learjet, Inc.*, 575 U.S. 373, 376 (2015). "Congress therefore has 'the power to preempt state law' through federal legislation." *Marentette* v. *Abbott Labs., Inc.*, 886 F.3d 112, 117 (2d Cir. 2018) (quoting *Arizona* v. *United States*, 567 U.S. 387, 399 (2012)). Such preemption is either express, *i.e.*, "through express language in a statute," or implied, "where, as here, a statute does not refer expressly to preemption," but preemption is a necessary consequence of the statute and federal regulatory framework. *Oneok*, 575 U.S. at 376-77.

Plaintiffs' claims in this case, which are brought in the shadow of the FDCA, implicate two distinct types of preemption. The first stems from the requirement, set forth in Section 337(a) of the FDCA, that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). "What this provision reflects is that only the federal government — not private parties — may enforce violations of the FDCA." *Patane* v. *Nestlé Waters N. Am., Inc.*, 314 F. Supp. 3d 375, 385 (D. Conn. 2018) (citing *POM Wonderful LLC* v. *Coca-Cola Co.*, 573 U.S. 102, 109 (2014) (noting that "the FDCA and its regulations provide the United States with nearly exclusive enforcement authority")).

Accordingly, "[a]lthough [Section] 337(a) does not expressly preempt state law, it has long been understood to have an implied preemptive effect." *Patane*, 314 F. Supp. 3d at 385 (citing *Buckman Co.* v. *Pls. Legal Comm.*, 531 U.S. 341, 349 n.5 (2001) (recognizing that the FDCA "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with" FDCA requirements)). The Second Circuit has therefore held that, if a plaintiff's "true goal is to privately enforce alleged violations of the FDCA," she cannot bring a cause of action under state law. *PDK Labs, Inc.* v. *Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997). To withstand this strain of FDCA preemption, therefore, "claims must be based not on the FDCA, but on 'traditional state tort law which … predate[s] the federal enactments in question,'" or other state remedies that are parallel to, but not premised on, the FDCA. *Glover* v. *Bausch & Lomb Inc.*, 6 F.4th 229,

237 (2d Cir. 2021) (quoting *Buckman*, 531 U.S. at 352-53). On the other hand, the FDCA squarely preempts an action brought by a plaintiff seeking "to sue under a generic state law claim (such as for fraud, breach of contract, or unfair trade practices) that would not be actionable absent a violation of the FDCA standard." *Patane*, 314 F. Supp. 3d at 386-87.

Separate and apart from preemption via Section 337(a), the FDCA also preempts state-law actions in "situations where compliance with both state and federal law is a physical impossibility." *Marentette*, 886 F.2d at 117 (citing *Arizona*, 567 U.S. at 399). This type of preemption is commonly known as "conflict preemption." *Id.* Pertinent to the allegations of this case, while "manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times," *Wyeth* v. *Levine*, 555 U.S. 555, 579 (2009), the FDCA limits the ability of manufacturers to "unilaterally change the labels on their products" without prior FDA approval, *Gibbons* v. *Bristol-Myers Squibb Co.*, 919 F.3d 699, 707 (2d Cir. 2019). Manufacturers may, however, make certain additions to their labels absent FDA approval, pursuant to the FDA's "changes being effected" ("CBE") regulation, set forth at 21 C.F.R. § 314.70(c)(6)(iii). To avoid conflict preemption under the FDCA, then, Plaintiffs must allege "a state law failure-to-warn claim that depends on newly acquired information — information that [a defendant] could have added to [its] label without FDA approval" pursuant to the CBE regulation; otherwise, Plaintiffs' failure-to-warn claim would be preempted by the rules regulating the FDA's pre-approval process. *Gibbons*, 919 F.3d at 708 (citing *Wyeth*, 555 U.S. at 568-72; *In re*

Celexa & Lexapro Mktg. & Sales Practices Litig., 779 F.3d 34, 40-41 (1st Cir. 2015)).

ii. Plaintiffs' Theories Predicated on Therapeutic Equivalence Rely Exclusively on the FDCA and Are Therefore Preempted

Turning to Plaintiffs' allegations, the Court begins with those supporting the Sameness Misstatement, reflecting Plaintiffs' position that "the so-called 'Chantix' [that Defendant] sold ***was not*** identical to itself (*i.e.*, the FDA-approved Chantix)," due to the former's lack of therapeutic equivalence with the latter. (Pl. Opp. 26 (emphasis in original); *see also id.* at 8-9). As discussed above, this argument attempts to relitigate the finding of *Harris*, that "contaminated Chantix is still Chantix." 586 F. Supp. 3d at 241. Regardless of whether this attempt has successfully sidestepped the reasoning of *Harris*, Plaintiffs' arguments regarding therapeutic equivalence are exclusively predicated on federal standards and are thus preempted by the FDCA.[6]

[6] The Court recognizes that while Defendant strongly disputes Plaintiffs' arguments regarding therapeutic equivalence, it does so by relying on Judge Cote's holding in *Harris*, rather than on a separate argument regarding the viability of state-law claims predicated on the FDA's regulations regarding therapeutic equivalence. Still, "[w]hen an issue or claim is properly before the court, the court is not limited to the particular legal theories advanced by the parties, but rather retains the independent power to identify and apply the proper construction of governing law." *U.S. Nat'l Bank of Or.* v. *Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 446 (1993) (quoting *Kamen* v. *Kemper Fin. Svcs., Inc.*, 500 U.S. 90, 99 (1991)). To that end, the Court, in its discretion, construes Defendant's arguments as implicating the issue of preemption, given that the issue is evident from the face of the complaint, can be answered without the need for a fact-intensive analysis, and must be resolved in order to determine viability, *vel non*, of a number of Plaintiffs' legal theories. *See Melendez* v. *Sirius XM Radio, Inc.*, 50 F.4th 294, 300 (2d Cir. 2022) (observing that preemption "can [] support a motion to dismiss if the statute's barrier to suit is evident from the face of the complaint" (internal quotation marks and citation omitted)); *Pac. Gas & Elec. Co.* v. *State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 201 (1983) ("The question of preemption is predominantly legal[.]").

(a) Plaintiffs Fail to State A Parallel Claim for Therapeutic Equivalence

As discussed above, "to survive preemption, a state law claim must rely on an independent state law duty that parallels or mirrors the FDCA's requirement[s] … but must not solely and exclusively rely on violations of the FDCA's own requirements." *Patane*, 314 F. Supp. 3d at 386. To that end, claims "based on a representation of product equivalency … may [survive preemption] when 'the truth or falsity of the statements in question can be resolved through reference to standards other than those of the FDA,' but not 'where a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA.'" *Midlothian Lab'ys, L.L.C.* v. *Pamlab, L.L.C.*, 509 F. Supp. 2d 1065, 1085 (M.D. Ala. 2007). Accordingly, for Plaintiffs' theories relying on the concept of therapeutic equivalence to survive preemption, they must find their roots in standards other than those of the FDA.

A review of the pertinent allegations of the CAC, however, reveals nothing of the sort. Rather, Plaintiffs' argument proceeds in roughly the following manner: Plaintiffs acknowledge that Chantix was approved by the FDA, pursuant to an approval application that made no mention of nitrosamines or the possibility of any contamination. Next, Plaintiffs explain the concept of therapeutic equivalence by summarizing a policy statement issued by the FDA, which statement, reproduced in full, provides that:

> FDA classifies as therapeutically equivalent those drug products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are

> pharmaceutical equivalents in that they (a) contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations.

Orange Book Preface to 43rd Edition, U.S. FOOD & DRUG ADMIN. (Jan. 24, 2023). (*See* CAC ¶ 8; *see also* Pl. Opp. 8-9). This policy statement, in turn, references the FDA's actual regulations defining "therapeutic equivalents" as:

> [A]pproved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and [which] can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

21 C.F.R. § 314.3(b).

Finally, and nominally applying this standard, Plaintiffs maintain that the presence of nitrosamines in contaminated Chantix rendered those batches not therapeutically equivalent to FDA-approved Chantix. (*See* Pl. Opp. 9 (collecting citations to the CAC supporting Plaintiffs' allegations regarding therapeutic equivalence)). In particular, Plaintiffs allege that the presence of those nitrosamines rendered contaminated Chantix (i) not as safe and effective as FDA-approved Chantix, (ii) not bioequivalent to FDA-approved Chantix, and (iii) not manufactured under the same conditions as FDA-approved Chantix. (*Id.*). As a consequence of this difference, Plaintiffs assert that contaminated

Chantix was actually a new varenicline-containing drug that was not FDA approved, such that Defendant made the Sameness Misstatement by disseminating contaminated Chantix in packaging that represented that the varenicline-containing drug was, in fact, FDA-approved Chantix. (*See, e.g.*, CAC ¶¶ 137 (alleging that contaminated Chantix was a "new and unapproved drug with additional active ingredients (such as nitrosamines in the subject [Chantix]) [that] cannot have the same label as the brand-name [Chantix]"), 150 (alleging that contaminated Chantix should be understood as "a different, new unapproved drug not therapeutically equivalent to FDA-approved Chantix")).

Nowhere in the above argument, however, do Plaintiffs ever identify any "independent state law dut[ies] that parallel[] or mirror[] the FDCA's requirements," pertaining to therapeutic equivalence, vis-à-vis Chantix and contaminated Chantix. *Patane*, 314 F. Supp. 3d at 386. As such, Plaintiffs' exclusive reliance on the FDA's standard for therapeutic equivalence essentially amounts to an impermissible attempt to privately enforce provisions of the FDCA through state-law causes of action, and is therefore preempted. *Id.*

(b) Plaintiffs' Application of Therapeutic Equivalence Is Preempted Under *Buckman*

The Court's preemption finding on this point is independently bolstered by Plaintiffs' allegations attempting to apply the therapeutic equivalence standard in the context of the new drug approval process. As discussed below, "permitting such claims to proceed would 'skew the delicate balance of statutory objectives' the FDA seeks to achieve in enforcing the FDCA's

requirements," such that Plaintiffs' claims cannot go forward. *Glover*, 6 F.4th at 237 (quoting *Buckman*, 531 U.S. at 352-53 (alteration adopted)).

Under the FDCA, determinations of therapeutic equivalence are made predominantly by the FDA (and no other entity) primarily when considering applications for the approval of pharmaceuticals pursuant to the Abbreviated New Drug Application ("ANDA") process set forth in the Act. *See* 21 U.S.C. § 355(j)(7)(v)(I) (providing that "*the Secretary* shall make an evaluation with respect to whether such [applicant] drug is a therapeutic equivalent (as defined in [21 C.F.R. § 314.3]) to another approved drug product" (emphasis added)); *Orange Book Preface to 43rd Edition*, U.S. FOOD & DRUG ADMIN. ("[T]herapeutic equivalence evaluations … *reflect FDA's application of specific criteria* to the multisource prescription drug products … approved under Section 505 of the [FDCA]." (emphasis added)).

Under the ANDA process, a manufacturer seeking approval of a new pharmaceutical submits documentation to the FDA in connection with the manufacturer's request that the Agency determine that the new pharmaceutical is therapeutically equivalent to an existing, approved pharmaceutical, known as a reference listed drug ("RLD"), allowing the putative new drug to avoid the rigorous and resource-intensive evaluation process associated with the FDA's standard New Drug Application process. *See Determination that CHANTIX (Varenicline Tartrate) Tablets, 0.5 Milligram and 1 Milligram, Has Not Been Withdrawn From Sale for Reasons of Safety or Effectiveness*, U.S. FOOD & DRUG ADMIN., 88 Fed. Reg. 12384 (Feb. 27, 2023)

(summarizing the materials an ANDA applicant must submit to the FDA in connection with its petition for approval on the basis of equivalence). Upon its determination that a new drug is the therapeutic equivalent of an RLD, and its approval of that new drug, the FDA lists both drugs in a publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, more commonly known as the "Orange Book." *See Orange Book Preface to 43rd Edition*, U.S. FOOD & DRUG ADMIN. Prescribers and payors then rely on the Orange Book to understand when they might substitute one drug for another, for reasons of cost or availability, based on the FDA's determinations of therapeutic equivalence (rather than their own application of the standard). (*Id.*).

Nowhere in this multi-step process have Plaintiffs provided any authority to support their suggestion that therapeutic equivalence represents a standard, either at the federal or state level, by which a district court can evaluate an already approved product as an equivalent of itself (*i.e.*, FDA-approved Chantix against contaminated Chantix), or to suggest that therapeutic equivalence represents an ongoing duty to which manufacturers of a pharmaceutical are obligated to comply. Indeed, and directly to the contrary, "[t]he Second Circuit has suggested that it is improper for the district court to engage in the scientific inquiry required to determine whether two drugs are 'therapeutic equivalents.'" *United States* v. *Articles of Drug Consisting of Following: 5,906 Boxes*, 745 F.2d 105, 118 n.20 (1st Cir. 1984) (citing *Premo Pharm. Lab'ys, Inc.* v. *United States*, 629 F.2d 795, 803 (2d Cir. 1980)). In particular, the Second

Circuit in *Premo* expressly noted that "the entire statutory scheme [of the FDCA] envisages that the FDA will perform the difficult task of investigation and scientific evaluation usually required to determine whether a drug product is safe and effective." *Premo*, 629 F.2d at 803. As such, "[n]othing in the language of the [FDCA] or its legislative history suggests that it is the task of the courts to determine in the first instance whether a drug product is safe, effective or 'therapeutically equivalent' to an already approved drug." *Id.*

While *Premo*'s holding did not technically implicate the issue of preemption, its logic applies with equal force to preclude Plaintiffs' arguments in this case, which similarly entreat the Court to reach the necessary conclusion that the inadvertent addition of nitrosamines to Chantix rendered it a new drug that should have been approved by the FDA prior to its sale. (*See, e.g.*, CAC ¶ 150 (alleging that contaminated Chantix should be understood as "a different, new unapproved drug not therapeutically equivalent to FDA-approved Chantix")). Put simply, Plaintiffs ask the Court to make a determination, applying the FDA's own regulations, that an FDA-approved drug has lost its FDA-approved status in connection with an alleged manufacturing issue, even when the FDA itself has declined to make such a determination, and even advised patients to continue taking the medication notwithstanding the issue.[7] The Court rejects this invitation, as Plaintiffs' theory is both

[7] As a related matter, the Court is not convinced by Plaintiffs' conclusory argument that the safety profile of Chantix necessarily changed due to the presence of a nitrosamine contaminant, in light of the FDA's own announcements to the contrary. For example, the FDA has rebuked Plaintiffs' position that safety requires there to be no presence of nitrosamines in any drug product (CAC ¶ 11), observing that that "[u]ncertainty about the presence and acceptability of the level of a[nitrosamine] in drug products raises

unpersuasive in light of the facts alleged, and embodies a form of fraud-on-the-FDA theory that is preempted under *Buckman* and otherwise foreclosed by *Premo*. *See Glover*, 6 F.4th at 237 (observing that *Buckman* held that "plaintiffs' claims that the manufacturer had misled the FDA during the approval process were preempted because those 'fraud-on-the-FDA' claims 'exist[ed] solely by virtue of the FDCA disclosure requirements'"); *Premo*, 629 F.2d at 803 ("Under the scheme of the [FDCA] the ultimate determination of the safety of a drug is not a matter given to the courts, but one to be determined by the [FDA] upon the submission of an NDA [or ANDA]." (internal quotation marks and citation omitted)).[8]

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regulatory challenges and has led to some applicants … discontinuing drug products from the market," causing "disruptions in supply and access," "drug shortages," and "challenges [] impact[ing] patient access to medications." *Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NSDRIs), Guidance for Industry*, U.S. FOOD & DRUG ADMIN. 2 (Aug. 2023). In light of these concerns about shortages caused by an overly-cautious posture by manufacturers, the FDA has "recommend[ed] a risk-based safety assessment of [nitrosamines,] … recogniz[ing] that the [acceptable intake] limits recommended by the Agency and those generated by manufacturers and applicants may evolve with advances in science and generation of data for nitrosamines." *Id.*

More to the point, Plaintiffs' argument that the safety profile for Chantix changed due to the presence of nitrosamines is made considerably less plausible by the FDA's own specific determination that Chantix remained safe and effective for patients, and that the "[nitrosamine] impurity can be controlled within the acceptable intake limit by sponsors of varenicline products within the context of their particular applications." *Determination that CHANTIX (Varenicline Tartrate) Tablets, 0.5 Milligram and 1 Milligram, Has Not Been Withdrawn From Sale for Reasons of Safety or Effectiveness*, U.S. FOOD & DRUG ADMIN., 88 Fed. Reg. 12384 (Feb. 27, 2023). It is objectively reasonable for the FDA to have made such a determination, as Chantix is a medication intended for application over a short-term period only, and its recommended twelve- or twenty-four-week course falls well short of the seventy-year period upon which the FDA's daily intake levels are premised. (*See* Nitrosamine Guidance 9 n.30 (expressing the FDA's view that "a drug product with a [higher] maximum daily dose … with the same detected level of the same type of nitrosamine[,] would pose a greater risk than a drug product with a [lower] maximum daily dose," and further observing that "[a] drug product intended for only short-term use (*e.g.*, a 7-day course of an antibiotic) poses less risk than a drug product intended for chronic use")).

[8] Nor does it matter that Plaintiffs have disclaimed any allegations that Defendant violated a specific duty owed to the FDA, as it is Plaintiffs' exclusive reliance the FDA's

(c) The *Valsartan* and *Metformin* Litigations Are Distinguishable

Finally, Plaintiffs rely heavily on two non-binding decisions in *Valsartan* and *Metformin*, parallel nitrosamine-related actions, that Plaintiffs maintain establish the viability of claims predicated on therapeutic equivalence. (Pl. Opp. 29 (citing *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.* ("*Valsartan IV*"), MDL No. 2875, 2021 WL 307486 (D.N.J. Jan. 29, 2021); *In re Metformin*, 2022 WL 970281)). Upon its own review, however, the Court is not persuaded.

In *Valsartan*, generic formulations of the drug valsartan were approved pursuant to the FDA's determination of their bioequivalence to Diovan, a brand-name RLD, and thereafter marketed by manufacturers of the generic drug as bioequivalent to Diovan. The district court permitted the plaintiffs to press claims predicated on the manufacturer's representation that valsartan was equivalent to Diovan, in connection with the discovery that generic valsartan also contained a contaminant belying that equivalence. *See, e.g.*, *Valsartan III*, 2021 WL 222776, at *4 n.3, 11. *Metformin* also featured a generic drug that, like valsartan, was found to be contaminated, and the *Metformin* court similarly declined to dismiss the plaintiffs' claims based on the

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therapeutic equivalence standard "[as] a critical element in their case," that implicates preemption. *Buckman Co.* v. *Pls. Legal Comm.*, 531 U.S. 341, 353 (2001); *cf. In re Trader Joe's Tuna Litig.*, No. 16 Civ. 1371 (ODW), 2017 WL 2408117, at *3 (C.D. Cal. June 2, 2017) (finding plaintiffs' claims preempted where they relied exclusively on the FDA's "standard for pressed cake weight pursuant to 21 C.F.R. § 161.190," and plaintiffs alleged "that they would not have purchased [Defendant's product] had they known the cans' fill did not comply with FDA standards").

manufacturer's marketing of the generic drug as the "chemical equivalent to the Orange Book brand name [drug]." *In re Metformin*, 2022 WL 970281, at *11, 14 (citing *Valsartan III*, 2021 WL 222776, at *60)).

There are several reasons, however, why the logic of *Valsartan* and *Metformin* does not map onto the instant case. Most notably, the fact that those cases involved generic versions of brand-name drugs renders them distinguishable from the one at hand. That is, the generic drugs in both *Valsartan* and *Metformin* were approved pursuant to the ANDA process discussed above, in which the FDA determined, upon an application by the manufacturers, that the proposed generic drugs were therapeutically equivalent to their RLDs. *See, e.g.*, *In re Metformin*, 2022 WL 970281, at *11 n.22 (observing that plaintiffs' claims "center only on generic drugs, outlining the generic drug approval process and the requirement that generic drugs must demonstrate bioequivalence to the [reference listed drug]"); *Valsartan III*, 2021 WL 222776, at *11 ("[A] drug is prescribed as a generic of an Orange Book pharmaceutical [*i.e.*, a reference listed drug or RLD]; for the generic to get approved to be marketed, the generic has to be chemically and biochemically equivalent to the Orange Book drug."). Upon approval, the *Valsartan* and *Metformin* manufacturers each marketed their generics as therapeutically equivalent to, and thus interchangeable with, a separate RLD.

As the *Harris* court observed, Plaintiffs in the instant case have set their sights on brand-name Chantix, which is itself the reference listed drug in the Orange Book. Accordingly, Defendant's marketing and sale of the drug under

its brand name "confers no warranty that it is identical to anything except itself." *Harris*, 586 F. Supp. 3d at 244 (specifically distinguishing *Valsartan III*). The distinction between brand-name and generic pharmaceuticals identified in *Harris* is significant, as it qualitatively distinguishes the representations made by generic manufacturers from those made by brand-name manufacturers. Indeed, the *Metformin* court came to an analogous conclusion upon its own analysis of *Harris*. *In re Metformin*, 2022 WL 970281, at *11 n.22 (finding that *Harris*'s conclusions regarding a brand-name pharmaceutical were inapposite where plaintiffs had "sufficiently alleged that the labeling of a generic drug confers a warranty that there is the 'absence of a significant difference [from the brand-name drug],' such that contamination of a generic drug would constitute a breach of warranty").[9]

Moreover, the Court finds that Plaintiffs in this case have failed to plausibly allege that contaminated Chantix was not bioequivalent to FDA-approved Chantix. Plaintiffs' allegations suggest that bioequivalence requires the two drugs to be strictly identical. (*See* Pl. Opp. 29 (citing *In re Metformin*, 2022 WL 970281, at *14 (finding actionable misrepresentations arising from manufacturing defendants' statements that their "[metformin-containing drugs]

[9] While the Court finds that Plaintiffs' claims predicated on Chantix's listing in the Orange Book are preempted, and therefore does not reach their merits, it notes that Plaintiffs have provided little support for their theory that the mere listing of Chantix in the Orange Book plausibly establishes that Defendant engaged in an affirmative misrepresentation. (Pl. Opp. 10-11 (citing CAC ¶¶ 186-198, 223-224, 243, 256, 265-266, 272, 325, 332)). In particular, Plaintiffs fail to plausibly establish how the FDA's listing of Chantix as a *reference listed drug* in the Orange Book, a publication authored by the FDA, and setting forth the Agency's determinations regarding therapeutic equivalence, can be attributed to Defendant as an affirmative representation on its part.

were bioequivalent to their RLDs")); CAC ¶ 85 (alleging that the presence of nitrosamines rendered the two products not "bioequivalent"); *see also id.* ¶ 219). To the contrary, the FDA's regulations defining "bioequivalence" require only that there be no absence of significant differences concerning the drug's active ingredient. *See* 21 C.F.R. § 314.3(b) (defining "bioequivalence" as "the absence of a significant difference in the rate and extent to which the *active ingredient* ... becomes available at the site of drug action when administered at the same molar dose under similar conditions"). Under that standard, it cannot be the case that contaminated Chantix was any different from FDA-approved Chantix, given that (i) both formulations contained the same dosage of the active ingredient varenicline and (ii) Plaintiffs do not allege that the presence of nitrosamines somehow inhibited the active ingredient's pharmacological effect.

Taking the conclusions from the foregoing sections together, the Court finds that Plaintiffs' claims predicated on the concept of therapeutic equivalence constitute nothing more than an impermissible attempt to "privately enforce alleged violations of the FDCA," and must be dismissed. *PDK Labs.*, 103 F.3d at 1113; *see also In re Trader Joe's Tuna Litig.*, 289 F. Supp. 3d 1074, 1086 (C.D. Cal. 2017) ("Where, like here, a plaintiff's true purpose is to enforce federal regulations, masquerading as a state-law claim where the state has not adopted a parallel statutory scheme is not sufficient to escape preemption."). To find otherwise by accepting Plaintiffs' invitation to apply a superficial version of the standard would impermissibly intrude on the FDA's

authority to administer the new drug approval process, to determine the efficacy and safety of pharmaceuticals such as Chantix, and to delineate the approval-related consequences in connection with impurities or other manufacturing-related issues. *Premo*, 629 F.2d at 803-04.

Stripped of these theories, Plaintiffs have provided no support for their claims predicated on the Sameness Misstatement, *i.e.*, that Defendant made any affirmative misrepresentation in connection with its sale of contaminated Chantix under the brand name Chantix, and therefore no reason for the Court to depart from Judge Cote's reasonable conclusion that "contaminated Chantix is still Chantix." *Harris*, 586 F. Supp. 3d at 241.

iii. Plaintiffs' Theories Predicated on Chantix's Ingredients Label Are Preempted

Next, Defendant argues that preemption similarly bars Plaintiffs' challenges predicated on Defendant's failure to disclose nitrosamines on Chantix's label, which failure lies at the heart of the Active Ingredient Misstatement. As discussed above, to avoid so-called "conflict" preemption in this context, Plaintiffs "must plead 'a labeling deficiency that [Defendant] could have corrected using the CBE regulation.'" *Gibbons*, 919 F.3d at 707-08 (quoting *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 40-41 (1st Cir. 2015)); *see also Wyeth*, 555 U.S. at 579. That regulation

> allows drug manufacturers to change [a label] without the FDA's preapproval if the changes "add or strengthen a contraindication, warning, precaution, or adverse reaction," or "add or strengthen an instruction about dosing and administration that is intended to increase

> the safe usage of the drug product," in order to "reflect newly acquired information."

Wyeth, 555 U.S. at 591 (Thomas, J. concurring) (internal citations omitted) (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A), (C)). Put slightly differently, "a manufacturer may only change a drug label" pursuant to the CBE regulation (*i.e.*, without FDA approval) to "add or strengthen a contraindication, warning, precaution, or adverse reaction" in light of "sufficient evidence of a causal association" based on "newly acquired information." *Utts* v. *Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 659-60 (S.D.N.Y. 2016) (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A), (C)), *aff'd sub nom. Gibbons* v. *Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019). The CBE regulation defines "newly acquired information" as information not previously submitted to the FDA that "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to the FDA." 21 C.F.R. § 314.3(b). As set forth below, the Court finds that Plaintiffs in this case have failed to plead "a labeling deficiency that [Defendant] could have corrected using the CBE regulation," *Gibbons*, 919 F.3d at 707-08, rendering their claims based on Chantix's ingredients label preempted.

As an initial matter, the Court finds that the *Gibbons* framework for preemption of labeling-deficiency claims applies to this case. In their submissions on the instant motion, Plaintiffs disavow raising any tort-based failure-to-warn claims and suggest that *Gibbons* and the associated caselaw pertaining to implied preemption of labeling actions should be limited accordingly. (Pl. Opp. 20 ("Pfizer forces the proverbial square peg into a round

hole by inaptly citing products liability failure-to-warn jurisprudence about drug labeling changes. This is not a products liability case." (internal citation omitted))). But Plaintiffs' position that Defendant should be liable in contract and breach of contract for its failure to "properly identif[y] nitrosamines' dangers … in the first place," is simply the other side of the same coin. (Pl. Opp. 20; *see also* CAC ¶¶ 274, 302).

Regardless of how Plaintiffs have chosen to frame their claims, the fact remains that Plaintiffs seek to impose liability on Defendant through a finding that Defendant was under an obligation to label Chantix differently — specifically, in a manner other than that which was FDA-approved — in order to inform consumers of the newly-discovered nitrosamine contaminant. Accordingly, the Court finds that, to avoid the preemptive effect of the FDCA, Plaintiffs must satisfy the requirements set forth in *Gibbons*. That is, Plaintiffs must plausibly establish Defendant was in possession of newly acquired information sufficient to meet the standard set forth in the CBE regulation, such that Defendant could have hypothetically made the disclosures called for by Plaintiffs' claims. Yet Plaintiffs have alleged nothing of the sort.

In relevant part, the CBE regulation states that newly acquired information "must provide reasonable evidence of a causal association of a clinically significant adverse reaction," which "has a significant impact on therapeutic decision-making, such as a risk that is potentially fatal or otherwise serious." *McGrath* v. *Bayer Healthcare Pharms. Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019) (quoting 21 C.F.R. § 201.57(c)(6)(i)). This standard

incorporates the FDA's "recogni[tion] that '[e]xaggeration of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use of a beneficial drug … [and that] theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance." *Utts*, 251 F. Supp. 3d at 660 (quoting *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Device*s, 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008)).

In this case, Plaintiffs gesture at scientific literature regarding the adverse health outcomes associated with nitrosamines in a vacuum. Plaintiffs do not identify any studies, data, or other information evidencing the specific causal association between the nitrosamine contaminants in Chantix and a clinically significant adverse reaction from taking Chantix, as required by the CBE regulation. Indeed, Plaintiffs' position that the nitrosamines found in Chantix posed an immediate and significant health risk is belied by the FDA's own determination that such risks could be "controlled within the acceptable intake limit by sponsors of varenicline products [*e.g.*, Chantix] within the context of their particular applications." *Determination that CHANTIX (Varenicline Tartrate) Tablets, 0.5 Milligram and 1 Milligram, Has Not Been Withdrawn from Sale for Reasons of Safety or Effectiveness*, U.S. FOOD & DRUG ADMIN., 88 Fed. Reg. 12384-85. Similarly, the FDA's express guidance directing patients to continue taking Chantix notwithstanding the nitrosamine contamination also undercuts any argument by Plaintiffs that the information would have a significant impact on therapeutic decision-making. *See FDA*

Updates and Press Announcements on Nitrosamine in Varenicline (Chantix), U.S. FOOD & DRUG ADMIN. (advising "patients taking recalled varenicline [*i.e.*, Chantix] to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition," and further noting that "[t]he health benefits of stopping smoking outweigh the cancer risk from the nitrosamine impurity in varenicline").

Plaintiffs' allegations, taken together and in the context of the FDA's own actions (of which this Court may take judicial notice), fail to demonstrate a causal association between nitrosamine contamination and a "clinically significant adverse reaction," such that Defendant would have been permitted to implement a labeling change pursuant to the CBE regulation. *See Merck Sharp & Dohme Corp.* v. *Albrecht*, 587 U.S. 299, 315 (2019) (observing that "manufacturers cannot propose a change [under the CBE regulation] that is not based on reasonable evidence" of a causal association between the newly acquired information and a clinically significant adverse reaction); *McGrath*, 393 F. Supp. 3d at 168 (finding claims preempted where plaintiff pleaded only "the mere possibility" that the medication could cause an adverse reaction).

And even assuming that the newly acquired information (*i.e.*, the presence of nitrosamine contaminants in Chantix) was causally associated with a "clinically significant adverse reaction" (which it is not), Plaintiffs fail to plausibly allege that Defendant was in possession of that newly acquired information at any point prior to its decision to recall Chantix. Rather,

Defendant's actions between the FDA's issuance of its Nitrosamine Guidance and Defendant's announcement of its voluntary recall suggest that Defendant responded to the FDA's emerging guidelines by timely investigating the potential contamination of its product and opting to address the issue with a recall, rather than an application pursuant to the CBE process. (*See generally* Nitrosamine Guidance 2-3 (discussing the evolution of the FDA's awareness of the issue of nitrosamine contamination)). *See also FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)*, U.S. FOOD & DRUG ADMIN. (providing the timeline of Defendant's announcements pertaining to the Chantix recall).

Plaintiffs are likewise unavailing in their theory that because Defendant was allegedly aware of the discovery of nitrosamines in other pharmaceuticals and the FDA's interest in regulating these contaminants, Defendant was essentially in possession of constructive knowledge of Chantix's contamination. (*See* Pl. Opp. 22). Notwithstanding the fact that the information circulating about nitrosamine contaminants was not Chantix-specific, and therefore did not provide Defendant with "reasonable evidence" of an adverse reaction in connection with the use of Chantix, Plaintiffs' theory is simply too attenuated to survive a motion to dismiss.

The Court thus concludes that Plaintiffs have failed to state a plausible claim that Pfizer was in possession of newly acquired information such that it should have unilaterally changed its label under the CBE regulation to disclose the presence of nitrosamines. Accordingly, Plaintiffs' claims predicated on the

Active Ingredient Misstatement are preempted. *See Gibbons*, 919 F.3d at 709 (affirming dismissal of "[p]laintiffs' complaints lack[ing] sufficient factual allegations to state a claim that is not preempted").

iv. Plaintiffs Have Plausibly Alleged Parallel Claims for Violations of the cGMPs

Finally, Defendant maintains that "claims premised on [Defendant's] alleged violations of cGMP regulations are impliedly preempted," as they amount to nothing more than an attempt to privately enforce regulations promulgated under the FDCA. (Def. Br. 26). In point of fact, Plaintiffs' cGMP-related theory of liability is sufficiently grounded in the law, as courts have recognized an established exception to preemption when it comes to certain claims for violations of cGMPs. In particular, while allegations predicated on generalized reference to cGMPs are too "unspecific to defeat preemption," *Garcia* v. *Bayer Essure, Inc.*, No. 21 Civ. 666 (MIS), 2023 WL 4235670, at *3 (D.N.M. June 28, 2023) (collecting cases), courts have recognized that allegations predicated on specific cGMPs, as incorporated by parallel state regulatory frameworks, may "survive preemption at the motion to dismiss stage." *McGee* v. *Johnson & Johnson*, 684 F. Supp. 3d 371, 381-82 (W.D. Pa. 2023) (collecting cases).

Drawing all inferences in Plaintiffs' favor, the Court finds that Plaintiffs have pleaded such parallel claims here. In particular, Plaintiffs identify two cGMPs that they maintain were violated in connection with the manufacture of Chantix: the first requiring the implementation of "a 'quality control unit' to

independently test drug product[s] manufactured by another company on contract" (CAC ¶ 122 (citing 21 C.F.R. § 211.22(a))), and the second requiring a manufacturer have in place "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess" (*id.* ¶ 123 (citing 21 C.F.R. § 211.100)). Plaintiffs further allege that the fact that contaminated batches of Chantix were able to reach the market, notwithstanding the FDA's guidelines regarding the acceptable levels of nitrosamines, indicates that there was a breakdown in Defendant's quality control and testing protocols as required by these cGMPs and incorporated by state law. (*See* CAC ¶¶ 176-185). The Court finds such allegations to be sufficient, "given the information to which Plaintiff[s] [have] access at this early point in the litigation, … to survive preemption at the motion to dismiss stage." *McGee*, 684 F. Supp. 3d at 381. A different conclusion might lie, however, after discovery in this matter, when Defendant has had the opportunity to adduce a more robust record supporting its compliance with both cGMPs.

d. Plaintiffs Have Plausibly Alleged Misrepresentations in Connection with cGMP Compliance

Finally, the Court briefly considers Defendant's remaining threshold argument: that Plaintiffs have not alleged that Defendant made any plausible misstatement or deceptive omission in connection with its manufacture and sale of Chantix. (Def. Br. 10). For the reasons set forth in the preceding section, the Court agrees with Defendant that the Sameness Misstatement and the Active Ingredient Misstatement are each predicated on arguments that are

preempted by the FDCA, and therefore cannot support Plaintiffs' corresponding claims, including for fraudulent and negligent misrepresentation, and breach of express warranty.

The same cannot be said for the cGMP Misstatement, which the Court finds to be adequately pleaded. As discussed above, Plaintiffs have identified the specific cGMPs setting forth requirements for quality control-related testing, and production and process control, which requirements Plaintiffs maintain were violated given that allegedly contaminated Chantix was allowed to reach the market. These allegations, accepted as true and considered together, "raise a reasonable expectation that discovery will reveal evidence" supporting Plaintiffs' claims. *Twombly*, 550 U.S. at 556.

Defendant's remaining arguments present fact-intensive challenges to the merits of Plaintiffs' claims, and therefore must be evaluated after discovery. In particular, Defendant may revisit its argument that the nitrosamine contamination could have arisen as a result of some other non-manufacturing related chemical reaction, and that Plaintiffs cannot establish that Defendant's suppliers actually failed to adhere to the cGMPs. (Def. Br. 7-8, 13). At the pleading stage, however, the Court finds that the cGMP Misstatement suffices as a specific, non-preempted misrepresentation for the purposes of the corresponding element in Plaintiffs' misrepresentation-related claims. That said, and as discussed below, certain of these claims fail for reasons independent of Plaintiffs' ability to identify an actionable misstatement.

3. Defendant's Claim-Specific Arguments

Incorporating the conclusions of the preceding section by reference, the Court next considers Defendant's specific attacks on Plaintiffs' individual claims.[10] The Court's analysis is complicated by the parties' reliance on generalized arguments regarding the elements of the various, predominantly state-law claims, coupled by broad citation to dueling appendices of cases from forty-three jurisdictions — which appendices, each side confidently asserts, support their invocation of either a given rule or its exception. Where possible, and as discussed below, the Court resolves these disputes upon its own review of the allegations and cited authority. However, for two discrete topics — the issues of pre-suit notice and the economic loss rule — the Court finds it necessary to order supplemental briefing from the parties before reaching a final decision.

a. The Court Dismisses Plaintiffs' Fraud Claims Due to Lack of Scienter

The Court begins with Plaintiffs' fraud claims. Broadly, Plaintiffs allege that Defendant was aware (or at least recklessly unaware) of the nitrosamine contamination of Chantix, but nevertheless opted to sell the contaminated product, and to continue to represent to the public that it was free from contaminants and manufactured pursuant to cGMPs. (*See* CAC ¶¶ 264-290). In moving to dismiss, Defendant maintains that Plaintiffs have failed to meet

[10] As Consumer Plaintiff Mary Allen, who was also a plaintiff in *Harris*, has voluntarily dismissed her claims pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i) (Dkt. #47), the Court need not reach Defendant's argument that Allen's claims are barred by *res judicata*.

the heightened pleading standard for fraudulent intent, and therefore cannot be permitted to move forward with their fraud claims. (Def. Br. 30-31). The Court agrees.

Federal Rule of Civil Procedure 9(b) provides that "a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). This particularity requirement imposes an additional, heightened pleading requirement beyond those set forth in Rule 8. *Compare* Fed. R. Civ. P. 8 (describing "General Rules of Pleading"), *with* Fed. R. Civ. P. 9(b) (setting forth requirements for "alleging fraud or mistake"). "In essence, Rule 9(b) places two further burdens on fraud plaintiffs — the first goes to the pleading of the circumstances of the fraud, the second to the pleading of the defendant's mental state." *Loreley Fin. (Jersey) No. 3 Ltd.* v. *Wells Fargo Secs., LLC*, 797 F.3d 160, 170 (2d Cir. 2015). As to the first requirement, the Second Circuit has held that "the complaint must '[i] detail the statements (or omissions) that the plaintiff contends are fraudulent, [ii] identify the speaker, [iii] state where and when the statements (or omissions) were made, and [iv] explain why the statements (or omissions) are fraudulent.'" *Id.* (quoting *Eternity Glob. Master Fund Ltd.* v. *Morgan Guar. Trust Co. of N.Y.*, 375 F.3d 168, 187 (2d Cir. 2004)). "As to the second, though mental states may be pleaded 'generally,' Plaintiffs must nonetheless allege facts 'that give rise to a strong inference of fraudulent intent.'" *Id.* (quoting *Lerner* v. *Fleet Bank, N.A.*, 459 F.3d 273, 290-91 (2d Cir. 2006)).

While Plaintiffs address the particularity requirement of Rule 9(b), they elide any meaningful discussion of the intent requirement. (*See* Pl. Opp. 12-13). Rather, to establish the requisite "strong inference of fraudulent intent," *Loreley*, 797 F.3d at 170, Plaintiffs rely on (i) generalized allegations related to the industry's awareness of the evolving issue of nitrosamine contamination in pharmaceutical manufacturing; (ii) the fact that manufacturers of different pharmaceuticals had discovered nitrosamines in their medications in previous years; and (iii) the related industry-wide requests by regulators that manufacturers conduct their own investigations to determine the possibility of contamination, (*see id.* at 10 (citing CAC ¶¶ 164-167)). These allegations are no different than those rejected in *Harris*, and (at best) establish that "[Defendant] may have known that its medication was at risk of contamination by late 2020." *Harris*, 586 F. Supp. 3d at 241. The allegations "do not show that [Defendant] knew or believed that Chantix was actually contaminated, particularly when the [P]laintiffs purchased Chantix in 2019 and the spring of 2020." *Id.*[11]

[11] As a notable example, the overwhelming majority of transactions in the exemplar payments chart for TPP Plaintiff County of Monmouth took place in a period that spanned the winter of 2015 through September 2020, when the FDA issued its Nitrosamine Guidance, with only a negligible amount following that date, including a number corresponding to APO-Varenicline, which was an Apotex-manufactured generic and not Chantix. (*See* CAC ¶ 49 (92% of Chantix transactions occurring pre-September 2020, 8% of transactions occurring post-September 2020))

And as compared to *Harris*, in which the individual plaintiffs specifically alleged purchase dates, the Consumer Plaintiffs in this case have hampered their efforts to meet the heightened pleading standard of Rule 9(b) by failing to allege specific dates of purchase, and, by extension, dates when the allegedly fraudulent misrepresentations were made to them. (*See* CAC ¶¶ 24-46).

Nor is the Court convinced by Plaintiffs' specific allegations. First, Plaintiffs invoke the June 30, 2021 Health Canada notice to establish that Defendant had been on notice of the issue prior to its recall announcement. (*See* CAC ¶¶ 169-173). That notice, however, was issued a mere two days prior to the FDA's own July 2, 2021 notice of Defendant's recall of Chantix, and such a short discrepancy in time establishes nothing more than the fact that Defendant acted promptly to investigate the issue in both Canada and the United States and took corrective action in both jurisdictions accordingly. It does not, however, plausibly establish that Defendant ever marketed Chantix with knowledge that it was contaminated. *See Clinger*, 2023 WL 2477499, at *15 (observing that "the basic essence of fraud [is] that a misrepresentation or omission has been made *with knowledge at the time it was made* that it was false or misleading"). Accordingly, it does not support the "strong inference of fraudulent intent" necessary to sustain allegations of fraud. *Loreley*, 797 F.3d at 170.

Plaintiffs are similarly unconvincing with their speculative allegations that "[Defendant] apparently did not begin testing or recalling its VCDs in the United States until July 2021." (CAC ¶ 14). At best, Plaintiffs are correct that Defendant began its voluntary recall of Chantix on July 2, 2021. (*Id.*). Plaintiffs offer nothing, however, to support their speculative allegation that Defendant only began testing its product in July 2021, in connection with that recall announcement. *See Eternity Glob. Master Fund Ltd.*, 375 F.3d at 187 (observing that while "[m]alice, intent, knowledge, and other condition of mind

of a person may be averred generally," this "leeway is not a 'license to base claims of fraud on speculation and conclusory allegations'"). Rather, the relatively short period of time between the FDA's directive to pharmaceutical manufacturers to begin testing for nitrosamines and Defendant's ultimate recall announcement neither shows "that [Defendant] had both motive and opportunity to commit fraud," nor "constitute[s] strong circumstantial evidence of [Defendant's] conscious misbehavior or recklessness." *Id.* (*See* Def. Br. 16 (citing Gulliver Decl., Ex. 2, Ex. 15 at 1-4)).

Finally, Plaintiffs suggest that Pfizer was on constructive notice of the contamination issue prior to September 2020, given discoveries of nitrosamine contamination in other pharmaceutical products, and therefore should be understood to have been recklessly unaware of the issue with Chantix. (*See, e.g.*, CAC ¶¶ 11, 168). To the contrary, the relatively incremental emergence of regulatory interest in the matter, as discussed above, belies Plaintiffs' conclusory assertion that the entire pharmaceutical industry should have been aware of the possibility of nitrosamine contamination upon the first discovery by a relatively discrete subset of manufacturers. These allegations, therefore, also cannot support any strong inference that Defendant knew or should have known that Chantix, itself, was or might have been contaminated, such that Defendant had "knowledge of [its] misstatements' falsity and an intent to induce reliance." *Loreley*, 797 F.3d at 176 (internal quotation marks and citation omitted).

The Court therefore finds that Plaintiffs have failed to clear the heightened bar for pleading fraudulent intent pursuant to Rule 9(b), and will therefore dismiss Plaintiffs' fraudulent misstatement and omission claims on that basis. As there is no heightened scienter requirement for Plaintiffs' remaining negligent misrepresentation claims predicated on the cGMP Misstatement, which misstatement the Court has already found to be actionable, the Court will permit those claims to proceed, subject to a potential renewed challenge under the economic loss rule, discussed *infra.*

b. Plaintiffs' Breach of Warranty Claims May Proceed, Subject to Plaintiff's Identification of Exceptions to Pre-Suit Notice Requirements

Next, the Court addresses Plaintiffs' warranty-based claims. As to express warranty, Plaintiffs essentially allege that Defendant made certain affirmative representations regarding Chantix that should be understood as express warranties, and that these warranties were breached when it became clear that the Chantix purchased by Plaintiffs was contaminated with nitrosamines. (*See* CAC ¶¶ 190-194, 218-233). These express warranties implicate the three categories of misstatements discussed above: the Sameness Misstatement, the Active Ingredient Misstatement, and the cGMP Misstatement. *See* Section B.1, *supra*. Next, Plaintiffs maintain that Defendant's sale of contaminated Chantix was done in breach of the implied warranty of merchantability and fitness for ordinary purpose. (*See* CAC ¶¶ 234-256).

Defendant attacks the warranty claims on five bases. *First*, Defendant maintains that the presence of nitrosamines in Chantix does not provide a basis for a breach of express warranty claim. (Def. Br. 31). *Second*, Defendant asserts that Plaintiffs have not established privity with Defendant, as neither the Consumer Plaintiffs nor the TPP Plaintiffs can plausibly allege that they purchased Chantix directly from Defendant. (*Id.*). *Third*, Defendant maintains that Plaintiffs have not alleged pre-suit notice. (*Id.*). *Fourth*, Defendant maintains that Plaintiffs cannot succeed in their implied warranty of merchantability claims, because the CAC does not allege that Chantix failed to fulfill its purpose of smoking cessation, or otherwise establish that the nitrosamine contamination harmed Plaintiffs. (*Id.* at 32). *Fifth*, and finally, Defendant maintains that the TPP Plaintiffs are not entitled to enforce warranty claims, as they cannot be considered the actual buyers of the Chantix. (*Id.*). The Court addresses each argument in turn.

i. Plaintiffs' Actionable Express Warranty Claims Are Limited to Those Arising from the cGMP Misstatement

Defendant's first argument — that the presence of nitrosamines does not provide a basis for a breach of express warranty — is resolved by the Court's earlier finding that Plaintiffs' theories of express warranty relying on either the Sameness Misstatement or the Active Ingredient Misstatement are preempted. *See* Section B.2.C, *supra*. Absent the Sameness Misstatement — *i.e.*, that contaminated Chantix was therapeutically inequivalent to FDA-approved Chantix — Plaintiffs have failed to provide any basis to rebut the *Harris* court's

finding that the "presence of a contaminant does not render the brand name on the label false." 586 F. Supp. 3d at 241. Similarly, Plaintiffs cannot ground liability in either the Active Ingredient Misstatement or their correlative theory that Chantix's label and related materials should have disclosed the nitrosamine contamination, since Defendant would not have been able to make such changes unilaterally under the FDA's CBE regulation.

That said, the Court finds that Plaintiffs may proceed with their theory of breach of express warranty predicated on the cGMP Misstatement. In particular, Plaintiffs have plausibly alleged that Defendant, by representing Chantix as FDA-approved, necessarily represented that Chantix was manufactured in accordance with certain cGMPs identified in the CAC and incorporated under state law. (*See* CAC ¶¶ 118-125, 152-158, 288). Should the record later permit, Defendant may press the argument that Plaintiffs cannot establish reliance on the cGMP Misstatement in connection with their purchasing decisions, as no reasonable consumer would have perceived (and thus relied on) Defendant's representation that Chantix was FDA-approved to also mean that it was manufactured in accordance with the specific cGMPs identified in the CAC. Still, "reasonable reliance is often a question of fact for the jury rather than a question of law for the court," and to that end the Court accepts Plaintiffs' allegations of reliance for the purposes of the motion to dismiss, and will permit this narrow set of claims to move forward. *STMicroelectronics, N.V.* v. *Credit Suisse Sec. (USA) LLC*, 648 F.3d 68, 81 (2d Cir. 2011); *see also Hesse* v. *Godiva Chocolatier, Inc.*, 463 F. Supp. 3d 453,

469-70 (S.D.N.Y. 2020) (observing that "[a]t the motion-to-dismiss stage, the [c]ourt cannot conclude that no reasonable consumer would rely on and be misled by" defendant's alleged express warranty (citing *Silva* v. *Smucker Nat. Foods, Inc.*, No. 14 Civ. 6154 (JLG), 2015 WL 5360022, at *10 (E.D.N.Y. Sept. 14, 2015) ("What a reasonable consumer's interpretation of a seller's representation might be is generally an issue of fact that is not appropriate for decision on a motion to dismiss.")).

ii. Summary Dismissal on the Basis of Privity Is Premature, Given Plaintiffs' Identification of Exceptions to the Privity Requirement

Defendant separately maintains that "Plaintiffs' express and implied warranty claims fail because they do not allege privity." (Def. Br. 31). The privity requirement reflects the broader fact that claims for express and implied warranty under the Uniform Commercial Code ("U.C.C."), as adopted by the various jurisdictions implicated in this suit, are "limited in [] scope … to warranties made by the seller to the buyer as part of a contract for sale." *Vermont Plastics, Inc.* v. *Brine, Inc.*, 79 F.3d 272, 280 (2d Cir. 1996) (quoting U.C.C. § 2-313, *cmt.* 2)). Still, there are a number of exceptions to the privity requirement, such as "[t]he third-party beneficiary exception, under which privity is not required if the manufacturer delivers to and attempts to meet the remote customer's requirements through a dealer." *MacNaughton* v. *Young Living Essential Oils, LC*, 67 F.4th 89, 101 (2d Cir. 2023). The scope of both the privity requirement and its exceptions varies, however, with each state's adoption of the U.C.C.

Both sides support their arguments with extensive, dueling charts. Defendant maintains that its chart proffers ironclad evidence of a strict privity requirement in each relevant jurisdiction. (*See* Def. Br., App'x A). Plaintiffs counter that "virtually all states' laws do not require privity or have well-recognized exceptions," as borne out by their own collection of cases. (Pl. Opp. 26 (citing Pl. Opp., App'x A)). More broadly, and more convincingly, Plaintiffs argue that the privity analysis is fact-based, and thus that "it is premature to rule on privity at this stage." (*Id.* (citing *Valsartan III*, 2021 WL 222776, at *12)). The Court agrees, especially in light of Defendant's failure to meaningfully address Plaintiffs' arguments regarding the exceptions to the privity requirement. (Def. Reply 12 (simply suggesting that "Plaintiffs' position regarding [Defendant's] well-supported privity argument is mistaken and '[c]ourts routinely dismiss breach of warranty claims at the motion to dismiss stage'" (quoting *Kaufman* v. *Pfizer Pharms., Inc.*, No. 02 Civ. 22692 (UU), 2010 WL 9438673, at *7 (S.D. Fla. Nov. 23, 2010)))).

Given the Court's obligation to credit the well-pleaded allegations of the CAC and draw all inferences in Plaintiffs' favor as to their invocation of the various exceptions to the privity requirement, the Court finds that any summary determination regarding privity would be premature. *See Valsartan III*, 2021 WL 222776, at *12 (declining to rule on the issue of privity where "the privity pleading requirements under a particular state's express warranty law … depend[] on varying fact conditions"). As this litigation progresses past the pleading stage, however, Plaintiffs will be obliged to support their privity

arguments with greater specificity, including in connection with Plaintiffs' anticipated motion for class certification, where Plaintiffs' proposed classes must account for these variations of state law.

iii. The Court Will Order Supplemental Briefing on the Issue of Pre-Suit Notice

Having addressed privity, the Court continues to the issue of pre-suit notice. Such notice reflects the requirement, set forth in U.C.C. § 2-607(3) and adopted by most states, that to recover on a breach of warranty claim, "the buyer must within a reasonable time after [she] discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." *McKay* v. *Novartis Pharm. Corp.*, 751 F.3d 694, 705 (5th Cir. 2014). Accordingly, "to adequately plead the pre-suit notice requirement, plaintiffs must provide factual allegations — such has the date and method plaintiffs sent a pre-suit notice — supporting the contention that they notified the defendant of the alleged breach within a reasonable time." *Anderson* v. *Unilever U.S., Inc.*, 607 F. Supp. 3d 441, 457 (S.D.N.Y. 2022) (alteration adopted).

As with the privity requirement (indeed, as with all other provisions of the U.C.C.), the contours of the notice requirement and the exceptions thereto differ across states, based on each state's adoption and interpretation of the U.C.C. While some states construe the requirement strictly, others may find that the act of filing a lawsuit may itself constitute sufficient pre-suit notice. *Compare, e.g.*, *Gregorio* v. *Ford Motor Co.*, 522 F. Supp. 3d 264, 284 (E.D. Mich.

2021) ("Michigan courts interpret the notice requirement strictly, requiring that 'upon discovering a breach, the buyer must provide reasonable pre-suit notice to even a remote manufacturer let the buyer be barred from any remedy.'"), *with, e.g.*, *Bednarski* v. *Hideout Homes & Realty, Inc.*, 709 F. Supp. 90, 92-94 (M.D. Pa. 1988) (recognizing that a third-party complaint may serve as adequate notice).

Defendant, in moving to dismiss, maintains that nowhere in the CAC do Plaintiffs allege having provided pre-suit notice in connection with their warranty claims. (*See* Def. Br. 31 (citing CAC ¶¶ 218-233 (express warranty); *id.* ¶¶ 234-256 (implied warranty)). In further support of this position, Defendant again proffers a chart of authorities purporting to establish the pre-suit notice requirements in 37 states, which chart is featured on pages five through seven of Appendix A to Defendant's memorandum of law in support of its motion to dismiss. (*See* Def. Br., App'x A at 5-7).

Plaintiffs fail to meaningfully address Defendant's argument, suggesting alternatively that (i) pre-suit notice was unnecessary, as Defendant had actual knowledge of its warranty breaches, (ii) Plaintiffs had, in fact, served demand letters in connection with the CAC and prior to consolidation, and (iii) the individual complaints filed prior to consolidation also served as notice. (Pl. Opp. 26-27). The Court's inquiry is further complicated by Plaintiffs' failure to address Defendant's chart of authorities purporting to establish the pre-suit notice requirements in 37 states. Instead, Plaintiffs offer a truncated chart, addressing only 10 of the 37 states, seemingly due to Plaintiffs' mistaken

impression that Defendant had provided citations to relevant authorities for only those states.[12] (*Compare* Pl. Br., App'x B at 1 n.1 ("Defendant's chart referenced only the following states. For each of these states, Plaintiff has provided citations to statutes and case law contradicting or refuting Defendant's argument."), *with* Def. Br., App'x A at 1, 5-7).

Because the Court's resolution of the issue in Defendant's favor would be dispositive as to a large subset of Plaintiffs' express and implied warranty claims across the various states, and because of significant variances in the interpretation of the notice requirement among the states, the Court will order further briefing on the issue of the sufficiency of the pre-suit notice in this case, and permit Plaintiffs to provide a proper appendix of authority with respect to the remaining states.

That said, the Court rejects Plaintiffs' argument that notice is unnecessary because Pfizer was actually aware of the cGMP deficiencies giving rise to the warranty claims in this action. As discussed in the context of Plaintiffs' fraud claims, the mere fact that other products were being recalled and the FDA's increasing interest in the area cannot support a finding that Defendant was on actual or constructive notice regarding the nitrosamine contamination in Chantix, such that it would have had reason to believe its manufacturing processes were somehow compromised. *See* Section B.3.a, *supra*.

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[12] Indeed, this chart seems to respond to Defendant's provision of a chart setting forth notice requirements for state consumer protection statutes, pertaining to a different set of Plaintiffs' claims. (*See* Def. Br., App'x A at 1).

The Court likewise agrees with Defendant that the demand letters appended to Plaintiffs' opposition brief do not necessarily remedy the absence of allegations in the CAC that Plaintiffs provided the requisite notice. (Def. Reply 12 n.17 (noting that "a plaintiff may not shore up a deficient complaint through extrinsic documents submitted in opposition" to a defendant's motion to dismiss (quoting *Madu* v. *SocketWorks*, 265 F.R.D. 106, 122-23 (S.D.N.Y. 2010)))). Plaintiffs should therefore focus their supplemental submission on the existence of exceptions to the notice requirement, including those that excuse a failure to allege that pre-suit notice was given. Additionally, assuming the demand letters may be considered by the Court, both sides should address whether such letters should have been provided to Defendant pre-suit, *i.e.*, before the filing of the individual actions, or if their post-suit transmittal to Defendant was sufficient.

iv. Plaintiffs Have Plausibly Alleged That the Sale of Contaminated Chantix Violated the Implied Warranty of Merchantability

Moving on, the Court considers Defendant's argument that Plaintiffs' "implied warranty of merchantability claim fails because the CAC 'does not allege that Chantix failed to fulfill its purpose' of helping smokers quit," or otherwise establish that Plaintiffs were harmed by the nitrosamine contaminant. (Def. Br. 32). As discussed below, however, the Court finds that the issue of the merchantability of contaminated Chantix is premature for resolution at this juncture.

Section 2-314 of the U.C.C., as adopted by the various states, provides that a sale of goods by default comes with an implied warranty "that the goods shall be merchantable … if the seller is a merchant with respect to goods of that kind." U.C.C. § 2-314(1). (CAC ¶ 235 ("At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose.")). While the implied warranty of merchantability "does not require that the goods be perfect or that they fulfill a buyer's every expectation; [and] only requires that the goods sold be of a minimal level of quality," the inquiry into whether such a warranty has been breached "directs its attention to the purchaser's disappointed expectations." *Caronia* v. *Philip Morris USA, Inc.*, 715 F.3d 417, 433-34 (2d Cir. 2013) (applying New York law) (alteration adopted and internal quotation marks and citations omitted); *see, e.g.*, *Valsartan III*, 2021 WL 222776, at *14 n.13 (observing that the implied warranty of merchantability "is based on the buyer's reasonable expectation that goods bought from a merchant, when compared with other goods of that same kind, will be free of significant defects and perform in the way that goods of that kind should perform").

The Court must, at this stage of the litigation, credit Plaintiffs' well-pleaded allegations that a reasonable consumer would have expected the Chantix they purchased to have been free of contaminants and manufactured in accordance with the cGMPs, in addition to her broader expectation that Chantix perform in accordance with its clinical indications. *Cf. Clinger*, 2023

WL 2477499, at *16 ("[U]ltimately what a reasonable consumer would expect [from their product] is a question of fact that is not readily susceptible to resolution on a motion to dismiss." (internal quotation marks and citation omitted)). While Defendant's arguments to the contrary may hold more sway at a later stage in the litigation, they do not at this threshold stage foreclose the plausibility of Plaintiffs' allegations.

v. The TPP Plaintiffs Have Plausibly Alleged Their Entitlement to Enforce Warranty Claims

Finally, the Court considers Defendant's narrower argument that the TPP Plaintiffs are not entitled to enforce warranty claims. (Def. Br. 32). Defendant makes this argument primarily by identifying the *Rezulin Products Liability Litigation*, in which case the district court found, at summary judgment, that health benefit providers were not buyers within the meaning of the UCC, and this could not enforce the UCC's remedies for breach of express and implied warranty. (Def. Br. 32 (citing *In re Rezulin Prod. Liab. Litig.*, 390 F. Supp. 2d 319, 331-34 (S.D.N.Y. 2005))). While Defendant is not wrong to have identified the issue, consideration of the sufficiency of Defendant's argument is fact-intensive, and requires discovery into the interrelationship between and among the TPP Plaintiffs, their beneficiaries, and the suppliers of Chantix. Indeed, in the *Rezulin* litigation itself, the Second Circuit vacated the district court's earlier dismissal of the case on the "financial intermediaries" theory, finding that "on a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the court is obliged to accept as true [the TPP Plaintiffs'] assertion that they were, in fact,

the purchasers of the drug." *Desiano* v. *Warner-Lambert Co.*, 326 F.3d 339, 350-51 (2d Cir. 2003) (observing that "[the Second Circuit], like several other courts, ha[s] indicated that in a variety of contexts [third-party payor plaintiffs] are the buyers" of the relevant drug (collecting cases)). Should it become apparent after discovery that, as in *Rezulin*, the contractual relationship of the TPP Plaintiffs and their patients was delineated such that the TPP Plaintiffs "gained no rights in the drugs," and thus could not qualify as buyers under the UCC, the Court will readily entertain Defendant's motion for summary judgment on Plaintiffs' breach of warranty claims on such basis. *In re Rezulin*, 390 F. Supp. 3d at 332-33.

c. The Court Dismisses Plaintiffs' Claims Under the Magnuson-Moss Warranty Act

Having addressed Defendant's challenges to Plaintiffs' state-law warranty claims, the Court now turns to Defendant's challenge to the sufficiency of Plaintiffs' claims for breach of the federal Magnuson-Moss Warranty Act ("MMWA"), 15 U.S.C. §§ 2301-2312. (Def. Br. 32-33). On this issue, the Court focuses its analysis on Defendant's argument that the FDCA bars application of the MMWA.[13]

Broadly speaking, the MMWA provides for a private right of action if a consumer is damaged based on a supplier's failure to comply with its

[13] The Court rejects Defendant's assertion that Plaintiffs' Magnuson-Moss Warranty Act claims cannot go forward because Plaintiffs' warranty claims must fail. The Court previously found that Plaintiffs may proceed with certain claims for breach of express and implied warranty, and that Plaintiffs have plausibly alleged that, by marketing Chantix as FDA-approved, Defendant made a specific "written affirmation of fact or promise that 'affirm[ed] or promise[d] that [Chantix] [was] defect free." *Kamara* v. *Pepperidge Farm, Inc.*, 570 F. Supp. 3d 69, 81 (S.D.N.Y. 2021).

obligations under a written or implied warranty. *See* 15 U.S.C. § 2310(d)(1). By its own terms, however, the MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law." 15 U.S.C. § 2311(d). "If only a portion of a written warranty is so governed by Federal law, the remaining potion shall be subject to" the MMWA. *Id.*

Interpreting this provision in the FDCA context, "[c]ourts have concluded that warranties regarding products governed by the [FDCA] are not subject to the MMWA pursuant to [the MMWA's] preemption provision." *MSP Recovery Claims, Series LLC* v. *Exactech, Inc.*, No. 22 MDL 3044 (NGG), 2023 WL 4066635, at *4 (E.D.N.Y. June 14, 2023) (citing *Dayan* v. *Swiss-Am. Prods., Inc.*, No. 15 Civ. 6895 (DLI) (VMS), 2017 WL 1214485, at *2, *5 (E.D.N.Y. Mar. 31, 2017) ("[T]he [MMWA] claim is barred in any event by 15 U.S.C. § 2311(d) because the label is governed by the FDCA.")); *see also Hernandez* v. *Johnson & Johnson Consumer Inc.*, No. 19 Civ. 15679 (BRM) (TJB), 2020 WL 2537633, at *5 (D.N.J. May 19, 2020) (dismissing MMWA claim because MMWA is inapplicable to labelling of FDA regulated products, and "Plaintiffs' Complaint acknowledges the FDA regulates" the product); *Bates* v. *Gen. Nutrition Ctrs., Inc.*, 897 F. Supp. 2d 1000, 1002 (C.D. Cal. 2012) ("Defendants are correct that the [MMWA] claim should be dismissed because the [FDCA] governs written warranties on the labeling of [the products].").

Nor are Plaintiffs correct in their argument that the applicability of this preemption provision "turns on whether the VCDs are 'consumer products.'" (Pl. Opp. 28 (citing *Kanfer* v. *Pharmacare US, Inc.*, 142 F. Supp. 3d 1091, 1105

(S.D. Cal. 2015))). To the contrary, the preemption provision of the MMWA is concerned not with the general classification of products, but with whether a written warranty "is otherwise governed by Federal law." 15 U.S.C. § 2311(d). Here, it is undisputed that the labels for Chantix implicated in Plaintiffs' breach of warranty claims are regulated by the FDA, even if those labels are also subject, in part, to parallel state-law claims. Indeed, even the *Valsartan* decision, upon which Plaintiffs rely throughout their opposition brief, "recently endorsed the argument that the MMWA prohibits warranty claims involving FDA-regulated items." *Valsartan III*, 2021 WL 222776, at *21 (collecting cases). This Court therefore declines Plaintiffs' invitation to break from the well-reasoned judgment of the many courts who have previously ruled on this issue and dismisses Plaintiffs' MMWA claims in their entirety.

d. Defendant Has Not Established That Plaintiffs' State Consumer Protection Claims Must Be Dismissed

In connection with their warranty- and misrepresentation-based claims, Plaintiffs also allege companion violations of over 50 different state consumer protection laws. (*See* CAC ¶ 314 (collecting citations)). As Plaintiffs conceive of the issue, Defendant's sale of contaminated Chantix constituted either unfair competition or an unfair or deceptive act or practice, in violation of numerous state laws. (*Id.*). In opposition, Defendant raises a number of challenges that the Court finds to be either premature or unpersuasive, as set forth below.

i. Defendant Has Not Met Its Burden to Establish That State Class Action Bars and Pre-Suit Notice Requirements Require Dismissal of Plaintiffs' Claims

Defendant raises two threshold challenges to Plaintiffs' consumer protection claims. *First*, Defendant maintains that these claims fail as to those consumers who reside in states with statutes that specifically bar class actions. (Def. Br. 33).[14] *Second*, according to Defendant, the pre-suit notice requirements of ten other states independently bar Plaintiffs' claims, as Plaintiffs have failed to allege that they sent a pre-suit demand for relief. (*Id.*).[15]

Because this action is brought under this Court's diversity jurisdiction, Defendant's first argument implicates a conflict between Federal Rule of Civil Procedure 23 and various state laws. *See Erie Railroad Co.* v. *Tompkins*, 304 U.S. 64 (1938). "Under the *Erie* doctrine, federal courts sitting in diversity apply state substantive law and federal procedural law." *Retained Realty, Inc.* v. *McCabe*, 376 F. App'x 52, 55 (2d Cir. 2010) (summary order) (quoting *Gasperini* v. *Ctr. for Humanities, Inc.*, 518 U.S. 415, 427 (1996)). Specifically, in federal court, a federal procedural rule will govern "regardless of contrary state law," so long as it is "consonant with the Rules Enabling Act," *id.*, meaning that the federal rule does not "abridge, enlarge or modify any [state] substantive right," 28 U.S.C. § 2072(b). A rule is "procedural" if it "'governs only the

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[14] These states are Georgia, Louisiana, Mississippi, Montana, South Carolina, and Tennessee. (Def. Br. 33).

[15] These states are Alabama, California, Georgia, Indiana, Iowa, Maine, Massachusetts, Mississippi, Texas, and West Virginia. (Def. Br., App'x A).

manner and the means by which the litigants' rights are enforced,' not 'the rules of decision by which the court will adjudicate those rights.'" *In re Sept. 11 Litig.*, 802 F.3d 314, 340 (2d Cir. 2015) (quoting *Shady Grove Orthopedic Assocs.* v. *Allstate Ins. Co.*, 559 U.S. 393, 407 (2010) (plurality opinion)). However, a "federal rule … cannot govern a particular case in which the rule would displace a state law that is procedural in the ordinary use of the term but is so intertwined with a state right or remedy that it functions to define the scope of the state-created right." *Shady Grove*, 559 U.S. at 423 (Stevens, J., concurring).

Courts have found that Rule 23 — the federal rule governing the adjudication of class action claims — is procedural. *See Shady Grove*, 559 U.S. at 400, 398-99, 405-08 (plurality opinion); *Retained Realty, Inc.*, 376 F. App'x at 55 n.1. As such, this Court is obligated to apply Rule 23, so long as it does not "abridge, enlarge or modify any [state's] substantive right." 28 U.S.C. § 2072(b). The pertinent question, then, is whether the class-action provisions of the state consumer protection laws of Georgia, Louisiana, Mississippi, Montana, South Carolina, and Tennessee, all of which would govern in absence of the application of Rule 23, are "substantive" for the purposes of Section 2072(b), or are otherwise "so intertwined with a state right or remedy that [they] function[] to define the scope of the state-created right." *Shady Grove*, 559 U.S. at 423 (Stevens, J., concurring). (*See* Def. Br. 33 n.12 (citing Ga. Code Ann. § 10-1-399(a); La. Stat. Ann. § 51:1409(A); Miss. Code. Ann. § 75-

24-15(4); Mont. Code Ann. § 30-14-133(1)(a); S.C. Code Ann. § 39-5-140(a); Tenn. Code Ann. § 47-18-109(a)(1), (g))).

On this point, Defendant does not meaningfully engage with the actual details of the class action bars under each state's law, and instead cites a small collection of cases that it maintains forecloses any decision defying the substantive nature of each state's class action bar. (Def. Reply 13). Defendant's exclusive reliance on this scattered collection of authority is unpersuasive, however, as distinguishing between a procedural and substantive law is "a challenging endeavor," requiring specific consideration of the interaction between each state's class action bar and the specific remedy provided by the relevant law. *Liberty Synergistics, Inc.* v. *Microflo Ltd.*, 718 F.3d 138, 152 (2d Cir. 2013). Moreover, the Court's own review identifies caselaw conflicting with that presented by Defendant. *See, e.g.*, *Jones* v. *Varsity Brands, LLC*, No. 20 Civ. 2892 (SHL), 2023 WL 5662590, at *8-9 (W.D. Tenn. Aug. 31, 2023) (finding class action bar under the Tennessee Trade Protection Act is not substantive, and therefore is preempted by Rule 23); *In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d 772, 820-21 (N.D. Ill. 2017) (declining to dismiss plaintiff's Montana and South Carolina consumer protection laws claims on the basis of statutory class action bars); *In re Packaged Seafood Prods.*, 242 F. Supp. 3d 1033, 1086 (S.D. Cal. 2017) ("[T]he Court concludes that the [South Carolina Unfair Trade Practices Act] class-action bar is a procedural rather than substantive rule.").

In light of this sparse and disputed record, the Court finds that any decision as to the substantive or procedural nature of any state's class action bar would be premature. The same is true with respect to the issue of Plaintiffs' compliance with pre-suit notice requirements under the state consumer protection laws, which requirements are also vigorously disputed by Plaintiffs, who support their position with equally plausible authority, the specifics of which are largely unaddressed by Defendant. (*Compare* Pl. Opp. 31 n.33, *with* Def. Reply 13). As elsewhere, however, Plaintiffs will have to seriously contend with both topics in any motion for class certification, and the parties are advised that the Court will expect more substantive discussion from them at that time.

ii. Plaintiffs Have Sufficiently Alleged That TPPs Are Consumers for the Purposes of the State Consumer Protection Claims

Defendant asserts that the TPP Plaintiffs, as entities that merely funded a beneficiary's purchase of Chantix, do not qualify as "consumers" under the state consumer protection laws of at least nine states, and alternatively are barred from seeking damages in other states in light of the *Illinois Brick* doctrine's prohibition against indirect purchaser actions for damages. (Def. Br. 34; Def. Reply 13). Neither of Defendant's positions succeeds.

Defendant's first argument mirrors its claims with respect to the TPP Plaintiffs' ability to enforce warranty claims, and the Court similarly finds that Plaintiffs have, for the purposes of this motion, sufficiently rebutted

Defendant's argument. (*See* Pl. Opp., App'x B at 2-3).[16] Plaintiffs have adequately alleged that Defendant engaged in consumer-oriented conduct for the purposes of the motion to dismiss, given "[t]he standard for establishing consumer-oriented conduct is very liberal." *Williamson* v. *Stryker Corp.*, No. 12 Civ. 7083 (CM), 2013 WL 3833081, at *14 (S.D.N.Y. July 23, 2013) (citing *Oswego Laborers' Local 214 Pension Fund* v. *Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 24-25 (1995)). (*See* CAC ¶ 191 (alleging that "Defendant affirmatively misrepresented and warranted to purchasers through its websites, brochures, and other marketing or informational materials that [Chantix] complied with cGMPs")). Defendant's argument that it did not engage in consumer-oriented conduct because Chantix must be prescribed by a doctor, is fact-based, and thus best addressed after discovery.

Next, Defendant's invocation of *Illinois Brick* is unconvincing, as Defendant has provided no authority supporting its application to consumer protection claims such as those in this case. (Def. Br. 34). By way of background, the doctrine is rooted in the Supreme Court's holding in *Illinois Brick Company* v. *Illinois*, 431 U.S. 720 (1977), that indirect purchasers do not have antitrust standing to sue for damages under the Sherman Antitrust Act. Regardless of whether the TPP Plaintiffs qualify as indirect purchasers in this case, Defendant has failed to demonstrate that *Illinois Brick* has relevance

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16 The Court is also unpersuaded by Defendant's assertion that Plaintiffs are required to identify Second Circuit caselaw for the proposition that TPP Plaintiffs can bring consumer protection claims under these circumstances, as the pertinent caselaw for interpreting the boundaries of the various state consumer protection law lies principally with the highest court of each state, rather than the Second Circuit. (Def. Reply 14).

outside of the antitrust context. Indeed, while the cases identified by Defendant may have involved claims nominally brought under state consumer protection statutes, the substance of the claims concerned alleged antitrust violations, thereby distinguishing those cases from the one at hand. (*See id.* at 34 n.16; *id.*, App'x A).

e. The Court Dismisses Certain of Plaintiffs' Unjust Enrichment Claims as Duplicative

Defendant's challenges to Plaintiffs' unjust enrichment claims obtain a slightly greater degree of success. Here, Defendant principally argues that Plaintiffs' claims of unjust enrichment are duplicative, rather than pleaded in the alternative, given that the allegations that Plaintiffs use as support are repackaged versions of the allegations supporting Plaintiffs' other theories of liability in the CAC.[17] While the Court finds Defendant's arguments to be true for a number of states, there remain others that expressly permit such duplicative claims to be pleaded, or for which Defendant's authority is unconvincing at this stage.

[17] Defendant also argues that the TPP Plaintiffs cannot state a claim for unjust enrichment as they only reimbursed purchases of Chantix that were made by their beneficiaries, and thereby did not confer a benefit on Defendant. (Def. Br. 35; Def. Reply 15). This argument is premature, as "the mere fact that there has been no direct contact between a defendant and the plaintiff does not preclude a finding that the defendant received a direct benefit from that plaintiff." *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 851 (E.D. Pa. 2019) (citation omitted). Defendant's related position — that the Consumer Plaintiffs have not alleged that they purchased Chantix from Defendant, rather than a pharmacy or third-party retailer — is equally unpersuasive, as the "chain of distribution in the pharmaceutical industry is short, direct, and well understood," and Chantix is a brand-name pharmaceutical manufactured exclusively by Defendant. *Id.* (Def. Br. 35).

Taking a step back, the Court acknowledges that Federal Rule of Civil Procedure 8(d) permits claims to be pleaded in the alternative. Under this principle, a plaintiff may plead two different theories of liability, even if each theory is inconsistent with the other. This includes claims for unjust enrichment where, for example, a plaintiff is also pressing a claim for breach of contract, notwithstanding the fact that success on the breach of contract claim would negate a critical element of the unjust enrichment claim, and *vice versa*.

A claim for unjust enrichment is not validly pleaded in the alternative, however, where it is included as a "catchall cause of action to be used when others fail," *Harris*, 586 F. Supp. 3d at 246 (quoting *Corsello* v. *Verizon N.Y., Inc.*, 18 N.Y.3d 777, 790 (2012)), and merely "repackage[es] the same allegations" as those pleaded elsewhere in the complaint, *EQT Prod. Co.* v. *Magnum Hunter Prod. Co.*, 266 F. Supp. 3d 961, 976 (E.D. Ky. 2017). In these circumstances, an unjust enrichment claim is properly dismissed as duplicative. *See, e.g.*, *EQT Prod. Co.*, 266 F. Supp. 3d at 976. To validly plead an unjust enrichment claim in the alternative, therefore, a plaintiff must demonstrate how she could "succeed on her unjust enrichment claim and fail on her other claims." *English* v. *Danone N. Am. Pub. Benefit Corp.*, 678 F. Supp. 3d 529, 540 (S.D.N.Y. 2023) (citing *In re Skat Tax Refund Scheme Litig.*, 356 F. Supp. 3d 300, 325 (S.D.N.Y. 2019) ("A claim is alternative and not duplicative if a plaintiff may fail on one but still prevail on the other.")).

Turning to the allegations of the CAC, the Court finds that Plaintiffs have failed to demonstrate how their unjust enrichment claims are pleaded in the

alternative. Plaintiffs have simply alleged that "Defendant was unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for [Chantix]." (CAC ¶ 378). Virtually the same allegations were found to be duplicative in *Harris*. *See Harris*, 586 F. Supp. 3d at 246 ("The only allegations in the [complaint] specific to the unjust enrichment claim state that [Defendant] accepted and kept the money obtained from selling Chantix."). Moreover, Plaintiffs' allegations that Defendant acted unjustly arise entirely out of their allegations undergirding their other contract, tort, and statutory claims; "to the extent that [Plaintiffs' other] claims succeed, the unjust enrichment claim is duplicative; if [P]laintiffs' other claims are defective, an unjust enrichment claim cannot remedy the defects." *Del Rosario* v. *Sazerac Co.*, Inc., No. 23 Civ. 1060 (AS), 2023 WL 6318083, at *3 (S.D.N.Y. Sept. 28, 2023) (quoting *Corsello*, 967 N.Y.3d at 790).

Plaintiffs attempt to sidestep this issue with a conclusory allegation that there is "no adequate remedy at law for Plaintiffs and other Class Members, especially in the alternative that the lack of a quasi-contractual relationship or common-law duty is found not to exist between Defendant and Plaintiff and other Class Members." (CAC ¶ 380). For starters, this allegation merely offers a "formulaic recitation of the elements of a cause of action" for unjust enrichment, and therefore cannot support Plaintiffs' claim. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). Moreover, Plaintiffs' allegation that they may ultimately lack an adequate remedy is implausible, given that Plaintiffs have covered the proverbial waterfront with claims of negligent

misrepresentation, breach of express and implied warranty, and violation of state consumer protection laws. In this case, "there is no doubt that a remedy at law exists; the only issue is whether Plaintiff[s] can prove the required elements." *Del Rosario*, 2023 WL 6318083, at *4.

Accordingly, the Court finds that Plaintiffs have not successfully pleaded their unjust enrichment claims in the alternative, and will dismiss Plaintiffs' claims in those states for which Plaintiffs' cited authority simply concerns the ability to plead in the alternative, but for which further authority in each state confirms the appropriateness of dismissal because the unjust enrichment claims are subsumed within other claims in the CAC. Those additional states for which Plaintiffs' unjust enrichment claims must be dismissed are

Alabama,[18] Arizona,[19] Florida,[20] Georgia,[21] Kentucky,[22] New Hampshire,[23] New Jersey,[24] New York,[25] Tennessee,[26] Texas,[27] and Wisconsin.[28]

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18 *See Carn as Tr. of SpecAlloy Corp.* v. *Cooke, Cameron, Travis & Co., P.C.*, No. 18 Civ. 1004 (JEO), 2019 WL 8301975, at *9 (N.D. Ala. June 4, 2019) (dismissing unjust enrichment claims as duplicative of negligence and malpractice claims where "[t]he crux of all of those claims is the [plaintiff's] allegation that [defendant] … breached the applicable standard of care").

19 *See Sentinel Ins. Co., Ltd.* v. *Tzion*, No. 15 Civ. 208 (NVW), 2017 WL 1197108, at *7 (D. Ariz. Mar. 31, 2017) (finding plaintiff "cannot sustain a claim of unjust enrichment because an adequate remedy exists at law," and further observing that "[u]njust enrichment is not a doppelganger of every other tort").

20 *See Licul* v. *Volkswagen Grp. of Am., Inc.*, No. 13 Civ. 61686 (JIC), 2013 WL 6328734, at *7 (S.D. Fla. Dec. 5, 2013) ("A plaintiff may plead unjust enrichment as an alternative theory to a legal cause of action. However, where the unjust enrichment claim relies upon the same factual predicates as a plaintiff's legal causes of action, it is not a true alternative theory of relief but rather is duplicative of those legal causes of action." (citing *Weaver* v. *Mateer & Harbert, P.A.*, No. 09 Civ. 514 (TBS), 2012 U.S. Dist. LEXIS 104771, at *55-56, 2012 WL 3065362 (M.D. Fla. July 27, 2012), *aff'd*, 523 F. App'x 565 (11th Cir. 2013) (summary order))).

21 *See Gwinnett Cnty.* v. *Netflix, Inc.*, 367 Ga. App. 138, 150 (2023) (dismissing unjust enrichment claims as duplicative where such claims "necessarily follow[ed]" from plaintiffs' allegation that defendants violated the Georgia TV Act), *cert. denied* (Sept. 19, 2023).

22 *EQT Prod. Co.* v. *Magnum Hunter Prod. Co.*, 266 F. Supp. 3d 961, 976 (E.D. Ky. 2017) ("[E]ven if the Federal Rules of Civil Procedure permit alternative pleading, dismissal would still be appropriate because [Plaintiff] has not successfully plead claims in the alternative. It has simply repackaged Counts I through V in Count VII [alleging unjust enrichment].").

23 *See Chen* v. *C & R Rock Inc.*, No. 14 Civ. 114 (AJ), 2016 WL 1117416, at *2 n.5 (D.N.H. Mar. 22, 2016) (finding that "the plaintiff's unjust enrichment claim simply duplicates other allegations found in the complaint," such that "[those] claims are inapplicable to [the] case").

24 *See Harris*, 586 F. Supp. 3d at 246 ("[U]nder New Jersey law, unjust enrichment does not provide an independent cause of action under tort law."); *Zafarana* v. *Pfizer, Inc.*, 724 F. Supp. 2d 545, 561 (E.D. Pa. 2010) ("[I]n New Jersey, unjust enrichment is not a substitute for failed tort claims.").

25 *See Harris*, 586 F. Supp. 3d at 246 (finding unjust enrichment "not available where it simply duplicates, or replaces, a conventional contract or tort claim").

26 *Cf. Univ. of Tenn. Rsch. Found.* v. *Caelum Biosciences, Inc.*, 667 F. Supp. 3d 734, 754 (E.D. Tenn. 2023) (finding that plaintiff's "request [for declaratory judgment] is addressed through one of [plaintiff's] remaining substantive claims and will be dismissed as duplicative").

27 *See Berry* v. *Indianapolis Life Ins. Co.*, No. 08 Civ. 248 (JJB), 2011 WL 3555869, *9 (N.D. Tex. Aug. 11, 2011) (dismissing unjust enrichment claims as duplicative where plaintiff's "unjust enrichment claim rises and falls with the fraud claim such that the attempt to plead 'unjust enrichment' as a separate claim adds nothing").

Other states impose separate, but related, bars to unjust enrichment claims, pursuant to which "[r]elief under the theory of unjust enrichment is not available where there is an adequate legal remedy or where statutory standards for recovery are set by the legislature." *United States* v. *Bame*, 721 F.3d 1025, 1030 (8th Cir. 2013) (applying Minnesota law). For these states, "[t]he important question is whether another remedy is available, not whether the party seeking a remedy will be successful." *Ferrara Fire Apparatus, Inc.* v. *JLG Indus., Inc.*, 581 F. App'x 440, 443-44 (5th Cir. 2014) (summary order) (applying Louisiana law). As there is no doubt in this case that Plaintiffs have an adequate remedy at law, and the only doubt is as to their ability to prevail on the merits, Plaintiffs have proffered no basis to maintain their claims for unjust enrichment in these states. Accordingly, the Court will separately dismiss Plaintiffs' claims for unjust enrichment under the laws of Illinois,[29] Louisiana,[30] Minnesota,[31] and Puerto Rico.[32]

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28 *See Smith* v. *RecordQuest, LLC*, 989 F.3d 513, 520 (7th Cir. 2021) (affirming dismissal of Wisconsin unjust enrichment claim because it was "derivative of, and predicated upon" Wisconsin statutory claim).

29 *See Oyoque* v. *DePaul Univ.*, 520 F. Supp. 3d 1058, 1065-66 (N.D. Ill. 2021) ("Because it is an equitable remedy, unjust enrichment is only available when there is no adequate remedy at law." (quoting *Nesby* v. *Country Mut. Ins. Co.*, 346 Ill. App. 3d 564, 567 (2004))).

30 *See Zaveri* v. *Condor Petroleum Corp.*, 27 F. Supp. 3d 695, 699, 701 (W.D. La. 2014) ("[T]he availability of another remedy bars a plaintiff's claim for unjust enrichment, regardless of whether the plaintiff prevails in his pursuit of those other remedies."); *see also Reel Pipe, LLC* v. *USA Comserv, Inc.*, No. 18 Civ. 6646 (EEF), 2019 WL 127055, at *4 (E.D. La. Jan. 8, 2019) (dismissing unjust enrichment claim as duplicative where plaintiff alleged not only breach of contract, but "other claims, sounding in tort," against defendant, such that plaintiff was not "without a remedy at law").

31 *See United States* v. *Bame*, 721 F.3d 1025, 1030 (8th Cir. 2013) (applying Minnesota law)

32 *See Gov't of Puerto Rico* v. *Carpenter Co.*, 442 F. Supp. 3d 464, 478 (D.P.R. 2020) ("[T]he unjust enrichment doctrine is 'subsidiary to other remedies provided by law and is

Still, there are certain other states for which Plaintiffs' cited authority or the Court's own review of the caselaw reveals specific exceptions to the aforementioned rules prohibiting duplicative claims for unjust enrichment. Beginning with California law, the Ninth Circuit has expressly instructed courts to refrain from dismissing unjust enrichment claims at the pleading stage, as the fact that an unjust enrichment claim might be "duplicative of or superfluous to [the plaintiff's] other claims … [is] not grounds for dismissal." *Astiana* v. *Hain Celestial Grp., Inc.*, 783 F.3d 753, 762-63 (9th Cir. 2015). Similar conclusions have been adopted by courts applying Vermont and Washington law. *See Assoc. Elec. & Gas Ins. Servs. Ltd.* v. *Elec. Power Sys., Inc.*, No. 14 Civ. 68 (CR), 2014 WL 12717669, at *11 (D. Vt. Dec. 23, 2014) (Vermont law); *United States ex rel. Savage* v. *Wash. Closure Hanford LLC*, No. 10 Civ. 5051 (EFS), 2015 WL 5825966, at *13 (E.D. Wash. Oct. 6, 2015) (Washington law).

Under Colorado law, courts permit unjust enrichment claims where "the 'equitable remedy' sought by a [plaintiff's] unjust enrichment claim appears to be separate from any available remedy at law under the [remaining claims]." *Edwards* v. *ZeniMax Media Inc.*, No. 12 Civ. 411 (WYD), 2013 WL 5420933, *10 (D. Colo. Sep. 27, 2013); *see also Menocal* v. *GEO Grp., Inc.*, 113 F. Supp. 3d 1125 (D. Colo. 2015) (denying motion to dismiss unjust enrichment claim as duplicative where remedies sought were different). In this case, Plaintiffs seek

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unavailable if the plaintiff may seek other forms of relief.'" (quoting *Rivera-Muñiz* v. *Horizon Lines Inc.*, 737 F. Supp. 2d 57, 65-66 (D.P.R. 2010)).

disgorgement exclusively as a remedy under their unjust enrichment claims, and not in connection with their separate claims. (CAC ¶ 381). Plaintiffs have therefore satisfied the exception under Colorado law for the purposes of the motion to dismiss.

Delaware and Pennsylvania law each establish that "[a]t the pleadings stage, an unjust enrichment claim that is entirely duplicative of a [separate claim] … is frequently treated 'in the same manner when resolving a motion to dismiss.'" *Calma ex rel. Citrix Sys., Inc.* v. *Templeton*, 114 A.3d 563, 592 (Del. Ch. 2015); *Zakheim* v. *Curb Mobility LLC*, No. 22 Civ. 4594 (GAM), 2023 WL 3898867, at *6 (E.D. Pa. June 8, 2023) (observing that under Pennsylvania law, "'an unjust enrichment claim may be pled as a companion … to a claim of unlawful or improper conduct as defined by law' and 'the unjust enrichment claim will rise or fall with the underlying claim'" (quoting *Whitaker* v. *Herr Foods, Inc.*, 198 F. Supp. 3d 476, 493 (E.D. Pa. 2016))). Under that standard, where the Court declines to dismiss the predicate claims, it must also "conclude that it is reasonably conceivable that Plaintiff[s] could recover under [their theory of unjust enrichment]," and deny Defendant's motion on that basis. *Calma*, 114 A.3d at 592. Such is the case here, and so Plaintiffs may proceed with unjust enrichment claims under Delaware and Pennsylvania law.

Finally, there are a number of states that expressly permit pleading unjust enrichment and breach of contract claims in the alternative where there is doubt as to the existence of a contract, but do not opine as to whether the unjust enrichment claims would be rendered duplicative by further layering of

tort and statutory claims atop the contract claims, as discussed above.[33] Defendant may therefore renew this argument upon further clarification of Plaintiffs' warranty claims, or with additional state-specific authority regarding the viability of unjust enrichment claims brought alongside tort and statutory claims.

Summarizing the preceding analysis, the Court grants Defendant's motion to dismiss as to Plaintiffs' unjust enrichment claims in Alabama, Arizona, Florida, Georgia, Illinois, Kentucky, Louisiana, Minnesota, New Hampshire, New Jersey, New York, Puerto Rico, Tennessee, Texas, and Wisconsin. The Court declines to dismiss Plaintiffs' claims for unjust enrichment in California, Colorado, Delaware, Pennsylvania, Iowa, Maine, Michigan, Nebraska, Vermont, Washington, and West Virginia. Likewise, the Court declines to dismiss Plaintiffs' claims in those states not included in Defendant's Appendix: Connecticut, Indiana, Maryland, Massachusetts, Mississippi, Missouri, Montana, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Texas, Virginia. (*See* Def. Br., App'x A at 9-11).

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[33] *See, e.g.*, *Kehrer Bros. Constr., Inc.* v. *Intercoastal Roofing Sols., LLC*, No. 13 Civ. 85 (JAJ), 2013 WL 11740243, at *3 (S.D. Iowa Dec. 19, 2013) (observing that under Iowa law, a motion to dismiss "is not the proper stage in the proceedings to make a determination as to whether [plaintiff's] … unjust enrichment claims cover the same subject matter as the express contract"); *Maine Oxy-Acetylene Supply Co.* v. *Prophet 21, Inc.*, No. 01 Civ. 91 (MJK), 2002 WL 126625, at *8 (D. Me. Jan. 31, 2002) (Maine law); *Project Producers, LLC* v. *Owens*, No. 23 Civ. 10056 (LJM), 2023 WL 6397753, at *5 (E.D. Mich. Sept. 29, 2023) (Michigan law); *Johnson* v. *Climate Corp.*, No. 15 Civ. 3083 (RFR), 2016 WL 11654853, at *4 (D. Neb. Aug. 4, 2016) (Nebraska law); *Heater* v. *General Motors, LLC*, 568 F. Supp. 3d 626, 642 (N.D.W. Va. 2021) (West Virginia law).

f. The Court Will Order Supplemental Briefing Regarding the Economic Loss Rule

Finally, the Court considers Defendant's argument that Plaintiffs' various tort claims for negligent misrepresentation, negligence, and negligence *per se* are all barred by the economic loss rule. (Def. Br. 27-28). In particular, Defendant maintains that, because Plaintiffs seek only damages in connection with their purchases of Chantix, and not arising from any physical injury in connection with their consumption of Chantix, they must recover under contract, rather than tort law. (*Id.*). Indeed, the same conclusion was reached by Judge Cote in *Harris*, who found that "[b]ecause the plaintiffs claim only economic harm, rather than personal injury, the economic loss doctrine bars their negligent misrepresentation claim." 586 F. Supp. 3d at 243. Plaintiffs respond that they have sufficiently pleaded various exceptions to the economic loss doctrine, and alternatively that resolution of the issue requires fact-specific inquiries that are ill-suited for a motion to dismiss. (Pl. Opp. 34).

As with the issue of pre-suit notice, the Court's initial concerns are of a more practical nature, in light of the parties' relatively truncated briefing on what Defendant maintains is a dispositive issue. In particular, the parties' discussion of the issue is limited to five paragraphs across the three briefs, along with an extensive appendix provided by Defendant setting forth each relevant state's formulation of the economic loss doctrine, and a short collection of cases identified by Plaintiffs in support of their arguments pertaining to the doctrine's exceptions. (*See* Def. Br. 27-28; Pl. Opp. 34-35; Def. Reply 15).

The Court will therefore order more thorough briefing from the parties on the issue. In responding, the parties, and Plaintiffs especially, should address the following specific concerns. *First*, Plaintiffs' allegations of harm based on mere "expos[ure] to [nitrosamines] … , implicating future potential health consequences (*see, e.g.*, CAC ¶ 232), are almost certainly insufficient to satisfy the physical injury exception to the economic loss doctrine, and Plaintiffs would be wise to identify any authority supporting their exposure-based theory.

Second, the parties should address what the Court considers to be the persuasive analysis in the *Boeing 737 Max Pilots Litigation*, 638 F. Supp. 3d 838, 860-62 (N.D. Ill. 2022), finding inapposite similar exceptions to those invoked by Plaintiffs in this case, including the existence of a special relationship between an individual plaintiff and a manufacturer defendant by dint of defendant's participation in a "highly-regulated" industry. (*See, e.g.*, CAC ¶ 287 (maintaining that Defendant and consumers were in a special relationship in light of "Defendant's superior knowledge and economic position vis-à-vis the true nature of [contaminated Chantix]")). While the *Boeing* court was applying Illinois law, Defendant may argue, supported by the appropriate authority, that similar findings should follow under the other relevant states' applications of the rule. Plaintiffs may, of course, dispute the issue, but are advised of their obligation to provide a more thorough appendix than that contained in their opposition brief to the instant motion.

Third and finally, Defendant is advised to clarify those states in which negligent misrepresentation falls within the ambit of the economic loss rule, versus those states in which it may fall within an exception.

CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss the CAC is GRANTED IN PART and DENIED IN PART. In particular, Defendant's motion to dismiss Plaintiffs' claims for fraudulent misrepresentation is GRANTED, as is Defendant's motion to dismiss Plaintiffs' claims under the Magnuson-Moss Warranty Act. Accordingly, Counts III and IV are hereby DISMISSED with prejudice. Defendant's motion to dismiss Plaintiffs' unjust enrichment claims is GRANTED IN PART, and Plaintiffs' claims arising under the laws of Alabama, Arizona, Florida, Georgia, Illinois, Kentucky, Louisiana, Minnesota, New Hampshire, New Jersey, New York, Puerto Rico, Tennessee, Texas, and Wisconsin are hereby DISMISSED with prejudice.

Defendant's motion to dismiss Plaintiffs' claims on the basis of preemption is DENIED to the extent Plaintiffs' claims rely on the cGMP Misstatement and alleged violations of the specific cGMPs identified in the CAC. Plaintiffs' claims arising out of the Sameness Misstatement and the Active Ingredient Misstatement are preempted, and therefore not cognizable.

As to next steps, Plaintiffs shall provide supplemental letter briefs, not to exceed ten single-spaced pages, on the issue of pre-suit notice and the economic loss rule, on or before **June 28, 2024**. Defendant may provide a response, not to exceed ten single-spaced pages, on or before **July 26, 2024**.

Both parties may provide appendices of authority, as appropriate, and are advised to group their authorities, to the extent possible, to reflect commonalities across state laws with respect to the various exceptions to pre-suit notice requirements and the economic loss rule, respectively.

The Clerk of Court is directed to terminate the pending motions at docket entries 42 and 52.

SO ORDERED.

Dated: May 28, 2024
New York, New York

Katherine Polk Failla

KATHERINE POLK FAILLA
United States District Judge